UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number: 001-39509

Dyne Therapeutics, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**36-4883909**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1560 Trapelo Road Waltham, Massachusetts	**02451**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (781) 786-8230

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	DYN	Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☒ NO ☐

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of Common Stock held by non-affiliates of the registrant computed by reference to the price of the registrant's Common Stock as of June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $948 million (based on the last reported sale price on the Nasdaq Global Select Market as of such date). For this computation, the registrant has excluded the market value of all shares of Common Stock reported as beneficially owned by its executive officer and directors; such exclusion shall not be deemed to constitute an admission that any such person is an affiliate of the registrant.

The number of shares of Registrant's Common Stock outstanding as of February 27, 2026 was 165,027,119.

DOCUMENTS INCORPORATED BY REFERENCE

The Registrant intends to file a definitive proxy statement pursuant to Regulation 14A relating to the 2026 Annual Meeting of Stockholders within 120 days of the end of the Registrant's fiscal year ended December 31, 2025. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein.

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Cautionary Note Regarding Forward-Looking Statements and Industry Data

This Annual Report on Form 10-K, or this Annual Report, contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act and Section 21E of the Securities Exchange Act of 1934, as amended, that involve substantial risk and uncertainties. All statements other than statements of historical fact, contained in this Annual Report, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “should,” “target,” "will," “would,” or the negative of these words or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Annual Report include, among other things, statements about:

- the initiation, timing, design, progress and results of our research and development programs, preclinical studies and clinical trials;
- the anticipated timing of the submission and clearance of investigational new drug applications, or INDs, and comparable foreign applications for any product candidates we may develop;
- the timing of and our ability to submit applications for, obtain and maintain regulatory approvals for any product candidates we may develop;
- our estimates regarding expenses, future revenue, capital requirements, need for additional financing and the period over which we believe our cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses, debt service obligations and capital expenditure requirements;
- our ability to comply with restrictive covenants under our loan agreement, or the Loan Agreement, with Hercules Capital, Inc., or Hercules;
- our ability to satisfy interest and principal payments under the Loan Agreement;
- our plans to develop and, if approved, subsequently commercialize any product candidates we may develop;
- the potential advantages of our FORCE platform;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position and our expectations regarding our ability to obtain and maintain intellectual property protection;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- the impact of government laws and regulations;
- our competitive position and expectations regarding developments and projections relating to our competitors and any competing therapies that are or become available; and
- our ability to establish and maintain collaborations or obtain additional funding.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in this Annual Report, particularly in Item 1A. “Risk Factors” in this Annual Report, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Moreover, we operate in a competitive and rapidly changing environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Our

forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments we may make or enter into.

You should read this Annual Report and the documents that we have filed or incorporated by reference as exhibits to this Annual Report with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this Annual Report are made as of the date of this Annual Report, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

This Annual Report includes statistical and other industry and market data that we obtained from independent industry publications and research, surveys and studies conducted by independent third parties as well as our own estimates of the prevalence of certain diseases and conditions. The market data used in this Annual Report involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Our estimates of the patient population with the potential to benefit from treatment with any of our product candidates includes several key assumptions based on our industry knowledge, industry publications, third-party research and other surveys, which may be based on a small sample size and may fail to accurately reflect the addressable patient population. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions.

This Annual Report contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

Risk Factor Summary

Our business is subject to a number of risks that, if realized, could materially affect our business, prospects, operating results and financial condition. These risks are discussed more fully in the "Risk Factors" section of this Annual Report. These risks include, but are not limited to, the following:

- we will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts;
- our product candidates are in varying stages of preclinical and clinical development, and we have not completed clinical development of any product candidate. We do not expect to have a product candidate ready for commercialization at least until 2027, if ever. If we are unable to advance product candidates through preclinical studies and clinical trials, obtain marketing approval and ultimately commercialize them, or experience significant delays in doing so, our business will be materially harmed;
- we may encounter substantial delays in commencement, enrollment or completion of our clinical trials and the data from the clinical trials of our product candidates may fail to demonstrate sufficient safety and efficacy to warrant further development or satisfy the applicable regulatory authorities, which could prevent us from commercializing any product candidates we determine to develop on a timely basis, if at all;
- our approach to the discovery and development of product candidates based on our FORCE platform is unproven, and we may not be successful in our efforts to develop our product candidates;
- the outcome of preclinical studies and initial data from earlier-stage clinical trials may not be predictive of final results of clinical trials or future clinical trials and data from trials in one indication may not be predictive of results of clinical trials in other indications;
- if our product candidates cause undesirable side effects or have other unexpected adverse properties, such side effects or properties could delay or prevent us from conducting clinical trials or seeking or obtaining regulatory approval, limit the commercial potential of our product candidates or result in significant negative consequences to the extent such effects or adverse properties are observed following any marketing approval;
- our Loan Agreement contains restrictive and financial covenants that may limit our operating flexibility and our failure to comply with the covenants or other terms of the Loan Agreement, including as a result of events beyond our control, could result in a default under the Loan Agreement that could materially and adversely affect our business;
- we rely, and expect to continue to rely, on third parties to conduct some or all aspects of our product manufacturing, research, preclinical and clinical testing, and these third parties may not perform satisfactorily;
- we face substantial competition, which may result in others discovering, developing or commercializing products before us or more successfully than we do;
- our rights to develop and commercialize certain of our product candidates are subject or may in the future be subject, in part, to the terms and conditions of licenses granted to us by third parties. If we fail to comply with our obligations under current or future intellectual property license agreements or otherwise experience disruptions to our business relationships with our current or any future licensors, we could lose intellectual property rights that are important to our business; and
- if we or our licensors are unable to obtain, maintain and defend patent and other intellectual property protection for any product candidates or technology, or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully develop and commercialize our product candidates or our technology may be adversely affected due to such competition.

PART I

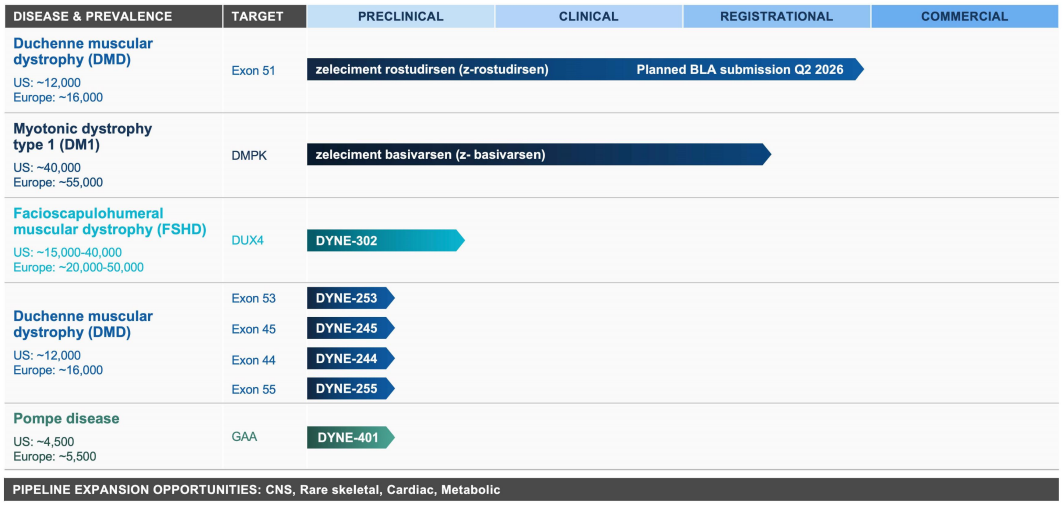
Item 1. Business.

Overview

We are a clinical-stage company focused on delivering functional improvement for people living with genetically driven neuromuscular diseases. Our proprietary FORCE platform is designed to leverage the transferrin receptor 1, or TfR1, to deliver targeted therapeutics to muscle tissue and the central nervous system, or CNS. The FORCE platform utilizes an antigen-binding fragment antibody, or Fab, targeting TfR1 conjugated to a payload that we rationally design to target the genetic basis of the disease we are seeking to treat. With our FORCE platform, we have the flexibility to deploy different classes of payloads (such as oligonucleotides and enzymes) with specific mechanisms of action that modify target functions. We currently leverage this modularity to focus on neuromuscular diseases with high unmet need, with etiologic targets and with clear translational potential from preclinical disease models to well-defined clinical development and regulatory pathways.

Using our FORCE platform, we are assembling a broad portfolio of product candidates, including product candidates being developed for Duchenne muscular dystrophy, or DMD, myotonic dystrophy type 1, or DM1, facioscapulohumeral dystrophy, or FSHD, and Pompe disease. In addition, we plan to expand our portfolio through development efforts focused on diseases involving the CNS, rare skeletal muscle diseases, and cardiac and metabolic muscle diseases, including some with larger patient populations. We have identified product candidates for each of our DMD (amenable to skipping exons 51, 53, 45, 44, and 55), DM1, FSHD and Pompe programs that are in varying stages of preclinical and clinical development.

The following table summarizes our portfolio:



Our product candidate zeleciment rostudirsen, or z-rostudirsen (also known as DYNE-251), is currently being evaluated in the DELIVER trial, a global Phase 1/2 clinical trial in patients with DMD amenable to exon 51 skipping, which is designed to be registrational. We plan to submit a biologics license application, or BLA, to the U.S. Food and Drug Administration, or FDA, for U.S. Accelerated Approval of z-rostudirsen for DMD patients who have mutations amenable to exon 51 skipping in the second quarter of 2026 based on dystrophin as a surrogate endpoint. We continue to expect a potential U.S. launch of z-rostudirsen in the first quarter of 2027, assuming the FDA grants priority review and FDA approval is received on the anticipated timeline. Further, we plan to initiate a global confirmatory Phase 3 clinical trial of z-rostudirsen in the second quarter of 2026, and we have aligned with the FDA on the Phase 3 trial design and protocol. We continue to pursue approval pathways outside of the United States for z-rostudirsen.

Our product candidate zeleciment basivarsen, or z-basivarsen (also known as DYNE-101) is being evaluated in the ACHIEVE trial, a global Phase 1/2 clinical trial in patients with DM1, which is designed to be registrational. We plan to submit a BLA to the FDA for U.S. Accelerated Approval of z-basivarsen for DM1 patients early in the third quarter of 2027. We anticipate a potential U.S. launch of z-basivarsen in the first quarter of 2028, assuming we receive favorable data from the ACHIEVE trial, priority review is granted, and FDA approval is received on the anticipated timeline. We plan to initiate a global confirmatory Phase 3 clinical trial of z-basivarsen in March 2026, and we have aligned with the FDA on the Phase 3 trial design and protocol. We continue to pursue approval pathways outside of the United States for z-basivarsen.

Our approach

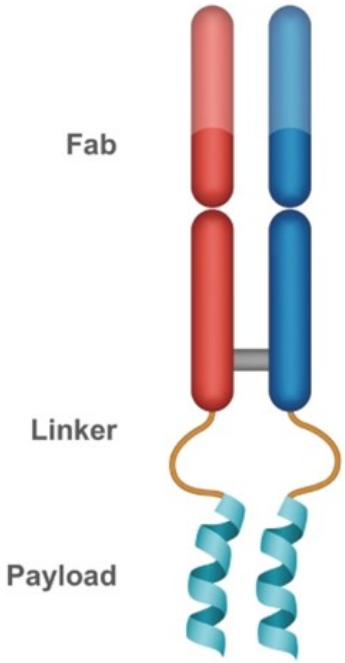
We have designed our proprietary FORCE platform using our deep knowledge of muscle biology. Our therapeutics consist of three essential components: a proprietary Fab, a linker and a payload that we attach to our Fab using the linker. We engineered our proprietary Fab to bind to TfR1 to enable targeted delivery to skeletal, cardiac and smooth muscle, and TfR1 binding may also enable delivery to the CNS. We connect the proprietary Fab to the therapeutic payload with a linker. We selected the linker for our DMD, DM1, and FSHD product candidates based on its clinically validated safety and efficacy in approved products, its serum stability and its ability to release the therapeutic payload within the muscle cell. For our Pompe product candidate, we selected a linker that effectively connects to the GAA enzyme payload. We attach the Fab and linker to a therapeutic payload that can be a phosphorodiamidate morpholino oligomer, or PMO, an antisense oligonucleotide, or ASO, a small interfering RNA, or siRNA, a small molecule, or a large molecule such as an enzyme, that we rationally select to target the genetic basis of disease to potentially stop or reverse disease progression. We use the same Fab for our product candidates which enables modularity of the platform.

While some therapeutics have been approved for the treatment of neuromuscular diseases, the development of these therapeutics has been limited by challenges in the delivery of the payload to the tissue or area of the CNS that requires therapy. To overcome these limitations, our FORCE platform utilizes the importance of TfR1, which is highly expressed on the surface of muscle cells, as the foundation of our novel approach of linking therapeutic payloads to our TfR1-binding Fab to deliver targeted therapeutics for muscle diseases. The mechanism of FORCE delivery is designed to utilize the natural biology of TfR1. We do not use membrane destabilizing agents to enter the cell or to escape the endosome. As a result, FORCE displays a distinct pharmacokinetic and pharmacodynamic profile, with the potential for a wide therapeutic index.

We have demonstrated proof-of-concept of our FORCE platform in our DELIVER and ACHIEVE clinical trials as well as in multiple *in vitro* and *in vivo* studies. In murine and non-human primate, or NHP, studies, we have delivered PMOs and ASOs to genetic targets within muscle tissue and observed durable, disease-modifying, functional benefit in preclinical models of disease. In DELIVER, z-rostudirsen has demonstrated best-in-class levels of dystrophin expression, exon skipping and percent dystrophin positive fibers while also showing improvement across multiple clinical measures including strength and time function tests. In ACHIEVE, z-basivarsen has demonstrated robust splicing correction and *DMPK* knockdown while also showing improvement across multiple clinical measures including myotonia, strength, timed function tests, and patient reported outcomes including measurements of the CNS manifestations of DM1.

The following graphic illustrates the three components of our therapeutics:

FORCE platform



Proprietary antibody (Fab)

Our proprietary Fab is engineered to bind to TfR1 to enable targeted delivery of nucleic acids and other molecules to skeletal, cardiac and smooth muscle. A Fab is the region of an antibody that binds to antigens. We selected a Fab antibody over monoclonal antibodies, or mAbs, due to its potential significant advantages when targeting TfR1 to enable muscle delivery, including enhanced tissue penetration, increased tolerability due to lower protein load and reduced risk of immune system activation due to the lack of the Fc domain, the portion of an antibody that interacts with the immune system, on the Fab. To identify the proprietary Fab we use in our product candidates, we generated and screened proprietary antibodies for selectivity to TfR1 in order to enhance muscle specificity and for binding to TfR1 without interfering with the receptor's function of transporting iron into cells. Binding to TfR1 may also enable delivery to the CNS.

Linker

The role of the linker is to connect, or conjugate, the Fab and the therapeutic payload, such as oligonucleotide or enzyme. As a result, it is critical that the linker maintain stability in serum and provide release kinetics that favor sufficient payload accumulation in the targeted muscle cell. For our DMD, DM1 and FSHD product candidates, we have selected the Val-Cit linker based on its clinically validated safety and efficacy in approved products, its serum stability and its endosomal release attributes. We believe that serum stability is necessary to enable systemic intravenous administration, stability of the conjugated oligonucleotide in the bloodstream, delivery to muscle tissue and internalization of the therapeutic payload in the muscle cells. In preclinical studies, our Val-Cit linker facilitated precise conjugation of multiple types of payloads to our proprietary Fabs, including PMOs, ASOs and siRNAs. For our Pompe product candidate, we selected a linker that effectively connects to the GAA enzyme payload. This broad flexibility enables us to rationally select the appropriate type of payload to address the genetic basis of each muscle disease. Additionally, our linker and conjugation chemistry allow us to optimize the ratio of

payload molecules attached to each Fab for each type of payload. We believe that our linker and conjugation chemistry will enable us to rapidly design, produce and screen molecules to enable new muscle disease programs.

Optimized payload

With our FORCE platform, we have the flexibility to deploy different types of therapeutic payloads with specific mechanisms of action that modify target functions. Using this modularity, we rationally select the therapeutic payload for each program to match the biology of the target, with the aim of addressing the genetic basis of disease and stopping or reversing disease progression. For instance, in our DM1 program, where the genetic driver of DM1 is mutant *DMPK* pre-mRNA located in the nucleus, we have determined to use an ASO because ASOs have advantages in degrading RNA in the nucleus when compared to siRNAs. In the case of our DMD program, we are utilizing an exon skipping PMO payload with the goal of enhancing dystrophin expression. For our FSHD program, we are utilizing a siRNA payload designed to reduce DUX4 expression. For our Pompe program, we are utilizing enzyme replacement therapy to address the deficiency of the lysosomal enzyme, acid alpha glucosidase, or GAA, the genetic basis of Pompe.

Advantages of our FORCE platform

Our FORCE platform is designed to deliver disease-modifying therapeutics for a broad portfolio of serious muscle diseases. We believe that our FORCE platform may provide the following potential advantages:

- Targeted delivery to muscle tissue and the CNS;
- Potent targeting of the genetic basis of disease to stop or reverse disease progression;
- Enhanced tolerability;
- Extended durability;
- Redosable administration;
- Well-established and scalable manufacturing; and
- Accelerated and efficient development enabled by use of a single Fab across multiple product candidates and programs.

Our strategy

Our goal is to become the leading neuromuscular disease company by advancing innovative life-transforming therapeutics for people living with genetically driven neuromuscular diseases. To accomplish this, we intend to continue building a team that shares our commitment to patients, to continue to enhance our platform and to advance our pipeline. The key elements of our strategy are to:

- Advance our co-lead product candidates for DMD and DM1 through development and to commercialization to offer meaningful benefit to patients;
- Progress our FSHD program to the clinic with the goal of ultimately offering a therapeutic for a disease with no approved treatments;
- Progress our Pompe program to the clinic with the goal of ultimately offering a therapeutic to provide meaningful benefit to patients;
- Establish a DMD franchise by expanding our DMD program to reach additional DMD patient populations;
- Expand our pipeline to additional product candidates and indications to fully exploit the potential of our proprietary FORCE platform;

- Selectively enter into strategic collaborations to maximize the value of our pipeline and our proprietary FORCE platform; and
- Build a sustainable leadership position in neuromuscular diseases with a deep connection to patients, caregivers, the research community and physicians.

Our culture and team

We have established a patient-focused culture that drives our shared mission of developing life-transforming therapeutics for people living with serious neuromuscular diseases. Our shared definition of success is simple: we do what we say we are going to do. We keep our commitments to patients, employees and other Dyne stakeholders. We endeavor to act with integrity and transparency.

Our management team is led by John Cox, our President and Chief Executive Officer, who brings over 30 years of leadership experience with life sciences companies; Erick Lucera, our Chief Financial Officer, who has more than 30 years of financial, operational and investment experience in the life science industry; Johanna Friedl-Naderer, our Chief Commercial Officer, who has more than 20 years of biopharmaceutical experience leading global commercialization and product launches in rare diseases; and Doug Kerr, M.D., our Chief Medical Officer, who has more than 25 years of expertise in early- and late-stage clinical development, with deep experience in neurology. Our organization is comprised of over 250 talented individuals with significant experience across discovery, preclinical research, manufacturing, clinical development, and commercial operations. We have also established scientific and clinical advisory boards comprised of leading experts in the fields of muscle disease drug discovery and development and nucleic acid therapeutics, who share our mission of delivering disease-modifying therapeutics for patients with neuromuscular diseases.

Our portfolio

We are creating a pipeline of product candidates and programs to address diseases with high unmet need with etiologic targets. Our initial focus is on DMD, DM1, FSHD and Pompe with potential pipeline expansion opportunities in additional diseases involving the CNS and rare skeletal muscle diseases, as well as cardiac and metabolic muscle diseases. In selecting diseases to target with our FORCE platform, we seek diseases with clear translational potential from preclinical disease models to well-defined clinical development and regulatory pathways, and where we believe that we would be able to commercialize any products that we develop and are approved with an efficient, targeted sales force. We have global commercial rights to all of our programs.

Duchenne muscular dystrophy (DMD)

Overview

We are developing product candidates under our DMD program to address the genetic basis of DMD by delivering a PMO to muscle tissue to promote the skipping of specific DMD exons in the nucleus, allowing muscle cells to create a more complete, functional dystrophin protein and to potentially stop or reverse disease progression. We believe that PMOs, with their preferential targeting of nuclear mechanisms, are the best payload to address nuclear exon skipping. In *in vitro* and *in vivo* preclinical studies, our PMOs when conjugated to a Fab targeting TfR1 have shown increased exon skipping, increased dystrophin expression, reduced muscle damage and increased muscle function. We are seeking to build a global DMD franchise by initially focusing on the development of our product candidate z-rostudirsen for patients with mutations amenable to skipping exon 51. Additionally, we are advancing four development candidates (DYNE-253, DYNE-245, DYNE-244 and DYNE-255) for the treatment of DMD amenable to skipping of exons 53, 45, 44 and 55, respectively, into IND-enabling studies. These programs are designed to enable the production of near full-length dystrophin in patients with DMD amenable to skipping of exons 53, 45, 44, or 55 by utilizing the same FORCE platform (Fab, linker, and payload chemistry) as z-rostudirsen.

Z-rostudirsen is currently being evaluated in the DELIVER trial, a Phase 1/2 global clinical trial in males with mutations amenable to skipping exon 51. The DELIVER trial began with a 24-week

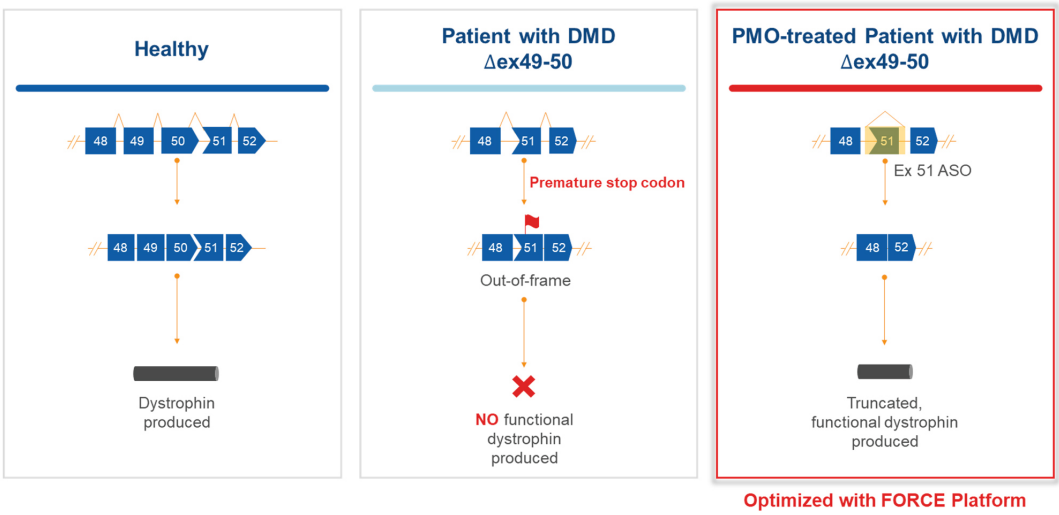
placebo-controlled multiple ascending dose, or MAD, portion, followed by a 24-week open-label extension, a 192-week long-term extension, and a registrational expansion cohort, or REC, designed to support Accelerated Approval in the United States. In September 2024, we announced the completion of the MAD portion of the trial, and in December 2025, we announced positive topline data from the REC portion of the trial.

Disease overview and prevalence

DMD is a monogenic, X-linked, disease caused by mutations in the gene that encodes for the dystrophin protein. Dystrophin protein is essential to maintain the structural integrity and normal function of muscle cells for walking, breathing and cardiac function. In patients with DMD, mutations in the dystrophin gene lead to certain exons being misread, resulting in the loss of function of the dystrophin protein. The reduction or absence of dystrophin leads to damage to muscle cell membranes, resulting in muscle cell death and progressive loss of muscle function.

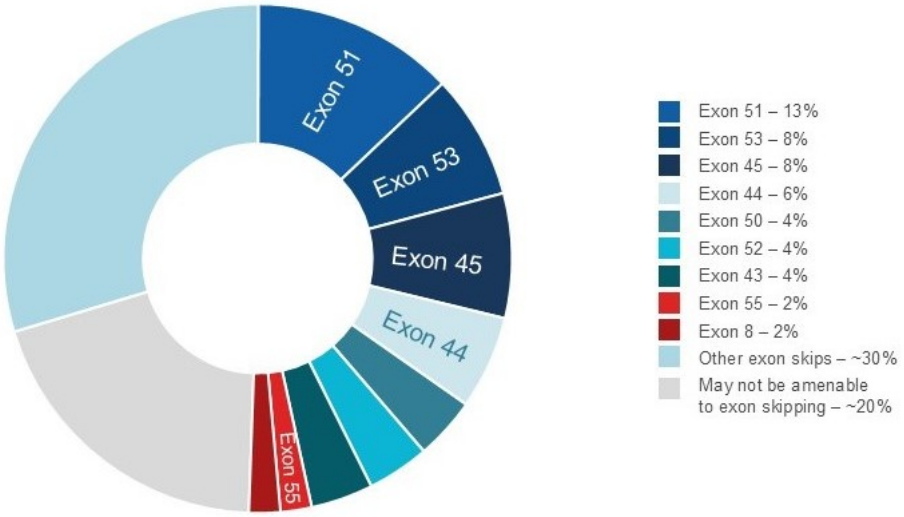
DMD symptoms typically begin to manifest with weakness and progressive loss of muscle function beginning in the first few years of life. Young boys experience progressive muscle wasting and have difficulty standing up, climbing stairs, running, breathing and performing daily functions. As the disease progresses the severity of damage to skeletal and cardiac muscles results in patients experiencing total loss of ambulation in the pre-teenage or early teenage years. Progressive loss of upper extremity function is often observed in the mid-to-late teens followed by respiratory and/or cardiac failure, resulting in death before the age of 30. The below graphic highlights the mechanism of exon skipping and resulting dystrophin expression in healthy individuals and in DMD patients and how our DMD program is designed to address the genetic basis of DMD.

Targeting the Genetic Basis of DMD



We estimate that DMD occurs in approximately one in every 3,500 to 5,000 live male births and that approximately 12,000 patients in the United States, and approximately 16,000 patients in Europe, have DMD. Approximately 80% of patients with DMD have DMD mutations amenable to exon skipping in the nucleus. Exons 51, 53, 45 and 44 represent nearly half of the total mutations observed in DMD that are amenable to exon skipping, as illustrated in the figure below.

Overview of DMD exons amenable to skipping



Current approaches and limitations

Currently, patients with DMD are treated with corticosteroids to manage the inflammatory component of the disease. There are four FDA-approved naked PMO-based oligonucleotide therapies, each addressing a specific mutation: EXONDYS 51 (eteplirsen), which is approved for the treatment of DMD patients amenable to exon 51 skipping, VYONDYS 53 (golodirsen), which is approved for the treatment of DMD patients amenable to exon 53 skipping, VILTEPSO (vitolarsen), which is approved for the treatment of DMD patients amenable to exon 53 skipping and AMONDYS 45 (casimersen), which is approved for the treatment of DMD patients amenable to exon 45 skipping. Additionally, there is one FDA-approved gene therapy for use in ambulatory patients with a confirmed mutation in the dystrophin gene, ELEVIDYS (delandistrogene moxeparvovec-rokl). Each of the four naked PMO-based oligonucleotide therapies requires weekly intravenous infusions and ELEVIDYS requires a one-time intravenous infusion. Eteplirsen, golodirsen and casimersen have demonstrated a less than 1% mean increase in dystrophin in clinical trials and vitolarsen has demonstrated an approximately 5% increase in dystrophin in clinical trials. The FDA-approved labels for all four drugs state that a clinical benefit has not yet been established and that continued approval may be contingent upon the verification of such clinical benefit in confirmatory clinical trials. In Europe, the EMA has rejected an application for approval of eteplirsen citing insufficient evidence of clinical benefit. In addition, a fourth drug, TRANSLARNA (ataluren), has only been conditionally approved in the European Union, or EU, Iceland and South Korea for non-sense mutations in DMD in ambulatory patients aged five years and older. However, the European Commission issued a decision to not renew the conditional marketing authorization for TRANSLARNA in March 2025, following a negative opinion by the Committee for Medicinal Products for Human Use, or CHMP. In addition, two recent pivotal Phase 3 trials of other PMO therapies in development for treatment of DMD failed to meet their primary endpoint in function (viltolarsen Phase 3 and golodirsen/casimersen Phase 3). Each of these approved PMO products seeks to address DMD through the exon skipping approach we are pursuing, but we believe their limited efficacy is due to poor muscle uptake and biodistribution. There are a number of product candidates in development, including product candidates in late-stage clinical development,

which seek to address DMD through the exon skipping approach we are pursuing, including naked oligonucleotides, targeted oligonucleotides and PMOs conjugated to charged peptides, as well as product candidates that seek to address DMD through gene editing and gene replacement with viral gene therapies and with other approaches. We believe that each of these approaches currently have significant limitations, and that there continues to be a high unmet medical need for new disease-modifying therapies.

Our approach

Our DMD program is designed to address the genetic basis of DMD by promoting the skipping of specific DMD exons in the nucleus, allowing muscle cells to create more complete, functional dystrophin protein. Under our DMD program, we are developing product candidates that incorporate our proprietary Fab targeting TfR1 conjugated to a PMO designed to promote the skipping of specific DMD exons in the nucleus. Existing clinical data generated by others supports the benefits of utilizing a single stranded ASO or PMO to skip the faulty exon in the nucleus of DMD patient cells. We believe our Fab targeting TfR1 allows for more efficient delivery of a PMO to skeletal, cardiac and smooth muscle cells, creating an opportunity to increase dystrophin expression, enable less frequent dosing and provide greater clinical benefit compared to current therapeutic approaches. We plan to develop our program candidates for DMD with a PMO, initially for exon 51 and in the future for other exon mutations including exons 53, 45 and 44.

Z-Rostudirsen

We are evaluating z-rostudirsen in the global Phase 1/2 DELIVER clinical trial for people living with DMD who are amenable to exon 51 skipping. Z-rostudirsen consists of a PMO conjugated to a Fab that binds to TfR1. Z-rostudirsen has been awarded Breakthrough Therapy, Fast Track, and Rare Pediatric Disease designations by the FDA as well as Orphan Drug designation from the FDA, the EMA and the Japanese Ministry of Health, Labour and Welfare for the treatment of DMD mutations amenable to exon 51 skipping.

Preclinical data

We have conducted multiple *in vitro* and *in vivo* preclinical studies of our FORCE platform in DMD that have shown increased exon skipping, increased dystrophin expression, reduced muscle damage and increased muscle function. We believe these data support the potential for z-rostudirsen to be a disease-modifying therapy for patients with DMD amenable to skipping exon 51.

In studies in the mdx mouse DMD model, a validated and widely accepted mouse model in DMD which has a mutation in exon 23, we observed that single intravenous doses of an exon 23-targeting PMO conjugated to a Fab targeting TfR1 which we refer to as FORCE-M23D, achieved robust, durable exon skipping in cardiac and skeletal muscles after a single dose. In NHPs, z-rostudirsen demonstrated a favorable safety profile and achieved robust exon skipping, especially in the heart and diaphragm muscles which weaken over time leading to mortality in people living with DMD.

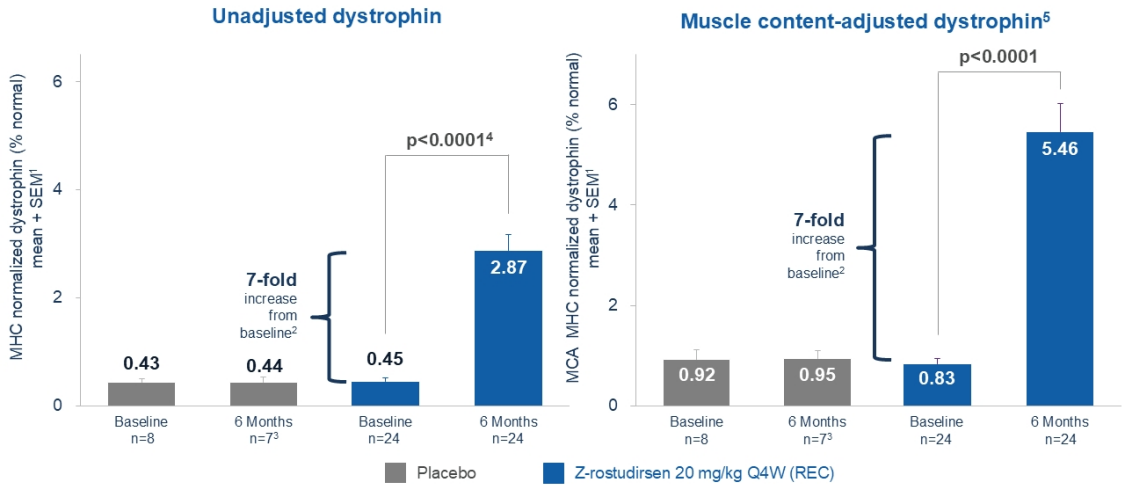
Phase 1/2 DELIVER Clinical Trial of Z-Rostudirsen in DMD

Z-rostudirsen is currently being evaluated in the DELIVER trial, a Phase 1/2 global clinical trial for DMD amenable to exon 51 skipping, which is designed to be registrational. DELIVER enrolled ambulant and non-ambulant males with DMD who are ages 4 to 16 and have mutations amenable to exon 51 skipping. The primary endpoints are safety, tolerability and change from baseline in dystrophin levels as measured by Western blot. Additional endpoints include pharmacokinetics and change from baseline in exon 51 skipping levels, muscle tissue percent dystrophin positive fibers, multiple assessments of muscle function, including rise from floor velocity, or RFF velocity, North Star Ambulatory Assessment, or NSAA, score, Stride Velocity 95th Centile and certain timed functional tests.

DELIVER began with a 24-week placebo-controlled MAD portion wherein participants were randomized to receive z-rostudirsen in doses ranging from 0.7 mg/kg to 40 mg/kg (approximate PMO dose) every four or eight weeks intravenously. Following the placebo-controlled period, MAD participants transitioned to

z-rostudirsen treatment in the 24-week open-label portion of the trial and the 192-week long-term extension. In September 2024, we announced the completion of the MAD portion of the trial, and in November 2024, we announced the initiation of the 20 mg/kg administered once every four weeks, or Q4W (approximate PMO dose) REC to support submission for Accelerated Approval in the United States.

We completed enrollment of 32 participants in the REC, of whom 24 were randomized to receive z-rostudirsen 20 mg/kg Q4W (approximate PMO dose) and eight were randomized to placebo, in March 2025. In December 2025, we reported that the REC met its primary endpoint of demonstrating a statistically significant increase in muscle content-adjusted dystrophin relative to baseline at six months ($p<0.0001$) with a mean absolute expression of 5.46% of normal, as shown in the image below:



1. Biopsies taken approximately 28 days after most recent dose.
2. Based on geometric mean.
3. One REC placebo participant sample could not be analyzed at week 25.
4. Prespecified nominal p-value with no adjustment for multiplicity.
5. Muscle content-adjusted dystrophin is equal to MHC normalized dystrophin divided by a percentage of muscle content. 6 months corresponds to week 25 for DELIVER.
In the image above, REC means registrational expansion cohort; MCA means muscle content-adjusted; MHC means myosin heavy chain; Q4W means every 4 weeks; and SEM means standard error of the mean.

In addition, in the REC, functional improvement was observed across multiple clinical endpoints, and lung function (as measured by forced vital capacity percent predicted, or FVC%p) remained stable with clear separation from placebo. Two of these endpoints, RFF Velocity and 10-Meter Walk/Run Velocity, both improved relative to placebo at six months with a nominal $p<0.05$, even though the study was not powered to demonstrate statistical significance in any of the functional measures (post-hoc analysis; the prespecified statistical analysis plan did not include formal hypothesis testing for any functional endpoint). Importantly, lung function, the loss of which is a leading cause of mortality in DMD, as measured by Forced Vital Capacity Percent Predicted was preserved at six months compared to a decline in placebo. In December 2025, we also reported long-term results from the MAD cohorts, including 24-month functional data from six participants that were randomized to the 10 mg/kg Q4W cohort and escalated to 20 mg/kg Q4W after six months, 18-month functional data from the six participants that were randomized to the 20 mg/kg Q4W cohort, and pooled 18-month functional data from both cohorts, showing sustained functional improvement across multiple functional endpoints out to 24 months.

In December 2025, we reported safety and tolerability data from the DELIVER trial based on 86 total participants in the DELIVER trial and followed for up to 36 months, including participants initially enrolled

in the MAD cohorts and the REC and who have transitioned to the longer-term extension portions of the trial. As of August 19, 2025, z-rostudirsen continued to demonstrate a favorable safety profile, and most related treatment emergent adverse events, or TEAEs, were mild or moderate. The most commonly reported related TEAEs were pyrexia (fever) and headache. No related serious TEAEs were observed in the REC.

We plan to submit a BLA to the FDA for U.S. Accelerated Approval in the second quarter of 2026 based on dystrophin as a surrogate endpoint. We continue to expect a potential U.S. launch of z-rostudirsen in the first quarter of 2027, assuming the FDA grants priority review and approval is received on the anticipated timeline. Further, we plan to initiate a global confirmatory Phase 3 clinical trial of z-rostudirsen in the second quarter of 2026, and we have aligned with the FDA on the Phase 3 trial design and protocol. We continue to pursue approval pathways outside of the United States for z-rostudirsen.

Myotonic dystrophy type 1 (DM1)

Overview

We are developing our product candidate, z-basivarsen, to address the genetic basis of DM1 by targeting the toxic nuclear *DMPK* RNA that causes the disease. Z-basivarsen consists of our proprietary Fab conjugated with a clinically-validated linker to an ASO and is designed to reduce the accumulation of *DMPK* pre-mRNA in the nucleus, release splicing proteins and potentially stop or reverse disease progression. In *in vitro* and *in vivo* preclinical studies supporting our DM1 program, we have observed a reduction in nuclear foci and toxic nuclear *DMPK* RNA, correction of splicing changes, reversal of myotonia, which is a neuromuscular condition in which the relaxation of a muscle is impaired, and enhanced muscle distribution. Z-basivarsen is currently being evaluated in the ACHIEVE trial, a Phase 1/2 global clinical trial of adult patients with DM1. ACHIEVE, which is designed to be a registrational trial, consists of a 24-week MAD randomized, placebo-controlled period, a 24-week OLE, a 96-week long-term extension and a registrational expansion cohort.

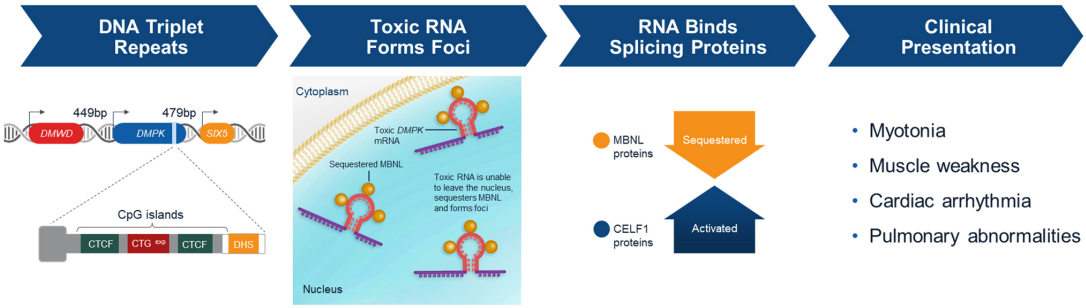
In January 2025, we announced the completion of the MAD portion of the trial and announced significant splicing correction at three months compared to baseline and observed functional improvement across multiple clinical endpoints at the registration dose of 6.8 mg/kg administered once every eight weeks, or Q8W. In June and October 2025, we reported positive long-term efficacy and safety data from adult DM1 patients enrolled in the MAD portion of the ACHIEVE trial including data from the 6.8 mg/kg Q8W cohort (n=6) at up to 12 months, showing robust and sustained improvement in myotonia as measured by video hand-opening time, or vHOT.

Disease overview and prevalence

DM1 is a monogenic, autosomal dominant, progressive disease that primarily affects skeletal, cardiac and smooth muscles. DM1 patients can suffer from various manifestations of the disease including myotonia, muscle weakness, CNS manifestations including fatigue, cognition and sleep complications, gastrointestinal, or GI, complications, cardiac arrhythmias, and respiratory problems.

DM1 is caused by an abnormal expansion in a region of the *DMPK* gene. Specifically, DM1 is caused by an increase in the number of CTG triplet repeats found in the 3’ non-coding region of the *DMPK* gene. The number of repeats ranges from up to approximately 35 in healthy individuals to many thousands in DM1 patients. The higher-than-normal number of triplet repeats form large hairpin loops that entrap the *DMPK* pre-mRNA in the nucleus and impart toxic activity, referred to as a toxic gain-of-function mutation. The mutant *DMPK* pre-mRNA sequesters in the nucleus, forming nuclear foci that bind splicing proteins. This inhibits the ability of splicing proteins to perform their normal function in the nucleus of guiding pre-mRNA processing of gene transcripts from many other genes. As a result, multiple pre-mRNAs that encode key proteins are mis-spliced. This mis-splicing in the nucleus results in the translation of atypical proteins which ultimately cause the clinical presentation of DM1. When nuclear *DMPK* levels are reduced, the nuclear foci that bind splicing proteins are diminished, releasing splicing proteins, allowing normal mRNA processing and translation of normal proteins, and potentially stopping or reversing disease progression. This disease process is illustrated below:

DM1: Genetic basis and clinical presentation



DM1 is estimated to have a genetic prevalence of 1 in 2,500 to 1 in 8,000 people in the United States and Europe, affecting approximately 40,000 people in the United States and over 55,000 people in the European Union. However, we believe that the patient population is currently underdiagnosed due to lack of available therapies as is observed for other rare diseases. DM1 is highly variable with respect to disease severity, presentation and age of onset.

We are advancing our own efforts to better characterize the actual DM1 patient population through a natural history study that we are sponsoring. We believe that the introduction of new therapies for DM1 will cause the diagnosis rate to improve, resulting in an increase in the overall prevalence estimates for the disease. Based on age of onset and severity of symptoms, DM1 is typically categorized into four overlapping phenotypes: late-onset; classical (adult-onset); childhood; and congenital (cDM1):

Overview of DM1 phenotypes

Phenotype	Clinical presentation	Estimated % of DM1 patients	Age of onset
Late-onset	• Myotonia • Muscle weakness • Cataracts	10%	40 - 70 years
Classical (Adult-onset)	• Muscle weakness and wasting • Myotonia • Cardiac conduction abnormalities • Respiratory insufficiency • Fatigue/Excessive daytime sleepiness • GI disturbance • Cataracts	65%	Early teens - 50 years
Childhood	• Psychological problems • Low IQ • Incontinence	15%	1 - 10 years
Congenital (cDM1)	• Infantile hypotonia • Severe generalized weakness • Respiratory deficits • Intellectual disability • Classic signs present in adults	10%	Birth

All DM1 phenotypes, except the late-onset form, are associated with high levels of disease burden and premature mortality. The clinical course of DM1 is progressive, and may become extremely disabling, especially when more generalized limb weakness and respiratory muscle involvement develops. Systemic manifestations such as fatigue, GI complications, cataracts and excessive daytime sleepiness greatly impact a patient's quality of life. As a result, DM1 leads to physical impairment, activity limitations and

decreased participation in social activities and work. Excluding congenital DM1 deaths, life expectancy ranges from 45 years to 60 years. Approximately 80% of early mortality is caused by cardiorespiratory complications. Respiratory failure due to muscle weakness (especially diaphragmatic weakness) causes at least 50% of early mortality, and cardiac abnormalities, including sudden death, account for approximately 30% of early mortality.

Current approaches and limitations

There are currently no disease-modifying therapies to treat DM1 that are approved and treatment is focused largely on symptom management or palliative therapies. There are a number of product candidates in development, including product candidates in late-stage clinical development, that also are focused on symptom management or palliative therapies and do not target toxic nuclear *DMPK* RNA, which is the genetic basis of the disease. In addition, delpacibart etedesiran is an antibody linked siRNA that targets the genetic basis of DM1 and is currently being evaluated in a Phase 3 clinical trial. There remains a high unmet medical need for new disease-modifying therapies.

Our approach - Z-Basivarsen

Our program is designed to address the genetic basis of DM1 by targeting the toxic nuclear *DMPK* RNA that is the cause of the disease. Our product candidate, z-basivarsen, consists of our proprietary Fab targeting TfR1 conjugated to an ASO to reduce the levels of mutant *DMPK* RNA in the nucleus, thereby releasing splicing proteins, allowing normal mRNA processing and translation of normal proteins, and potentially stopping or reversing disease progression. The ASO is a gapmer oligonucleotide that is designed to translocate to the nucleus, bind its complementary sequence on the *DMPK* RNA, recruit RNAseH1 to degrade *DMPK* RNA and thus reduce toxic nuclear *DMPK* RNA. We have chosen to develop our product candidate with an ASO because single-stranded ASOs preferentially target nuclear RNAs, which is essential for degradation of toxic nuclear *DMPK* RNA. Z-basivarsen has been awarded orphan drug designation for the treatment of DM1 by both the FDA and the European Medicines Agency, or EMA. The FDA has granted Fast Track and Breakthrough designations for z-basivarsen for the treatment of DM1.

Preclinical data

We have conducted extensive preclinical studies supporting the development of z-basivarsen in multiple preclinical disease models. In *in vitro* and *in vivo* preclinical studies, we observed a reduction of nuclear foci, correction of splicing and reversal of myotonia in disease models, as well as reduction of toxic human nuclear *DMPK* in a hTfR1/DMSXL DM1 mouse model developed by us. In NHPs, z-basivarsen demonstrated a favorable safety profile and achieved enhanced muscle distribution as evidenced by a reduction in wild-type *DMPK* RNA.

Phase 1/2 ACHIEVE Clinical Trial of Z-Basivarsen in DM1

Z-basivarsen is currently being evaluated in the ACHIEVE trial, a global Phase 1/2 clinical trial consisting of a 24-week MAD, randomized, placebo-controlled period, a 24-week OLE, a 96-week long-term extension, and a registrational expansion cohort. The primary endpoints of the MAD portion of the trial were safety and tolerability; with secondary endpoints of pharmacokinetics and pharmacodynamics, including change from baseline in splicing as measured by the composite alternative splicing index, or CASI-22, myotonia, as measured by vHOT, as well as multiple measures of muscle strength and function and patient-reported outcomes, including the Myotonic Dystrophy Health Index, or MDHI. In the MAD portion of the ACHIEVE trial, patients were randomized to receive z-basivarsen or placebo intravenously every four weeks or every eight weeks for 24 weeks, depending on cohort. Patient cohorts were dosed from 1.8 mg/kg to 6.8 mg/kg (approximate ASO dose). Following the MAD placebo-controlled period, patients transitioned to z-basivarsen treatment in the OLE portion of the trial and in the long-term extension.

In January 2025, we announced the completion of the MAD portion of the ACHIEVE trial in adults with DM1 and reported efficacy and safety data, including data from the 6.8 mg/kg Q8W cohort (n=8) at up to 6 months. At the 6.8 mg/kg Q8W dose, z-basivarsen resulted in significant splicing correction at 3 months

compared to baseline, early and robust improvement in myotonia at six months, improvement in multiple functional endpoints, beginning at 3 months and continuing at 6 months, and improvement in patient reported outcomes, including scales assessing CNS disease manifestations, at 6 months.

In June and October 2025, we reported positive long-term efficacy and safety data from adult DM1 patients enrolled in the MAD portion of the ACHIEVE trial, including data from the 6.8 mg/kg Q8W cohort (n=6) at up to 12 months. At the 6.8 mg/kg Q8W dose, z-basivarsen demonstrated robust and sustained improvement in myotonia as measured by vHOT as well as sustained improvements across multiple other endpoints. Treatment with z-basivarsen led to an improvement in vHOT of 3.3 seconds as compared to placebo at 6 months, and data demonstrated that mean improvements at 6 months were sustained at 12 months for vHOT, 10-Meter Walk/Run Test, or 10MWR, 5 Times Sit to Stand Test, or 5xSTS, MDHI, and Qualitative Muscle Testing, or QMT, which demonstrated a 10% improvement in strength at 6 months, increasing to 20% at 12 months relative to baseline. Improvements from baseline were also observed in the 9-Hole Peg Test, a measure of upper limb function focused on manual dexterity and coordination; QMT scores across both upper and lower extremities showing robust and sustained improvement; MDHI subscales of mobility, ability to do activities and upper extremity function showing robust and sustained improvement; and the Patient Global Impression of Change, and Clinician Global Impression of Change, scales showing improvement in overall disease burden.

In June 2025, we also reported updated safety and tolerability data from the 56 patients enrolled through the MAD and OLE portions of the ACHIEVE trial. As of the data cutoff date of April 23, 2025, z-basivarsen demonstrated a favorable safety profile. Additionally, the majority of treatment-emergent adverse events were mild or moderate, and no related serious treatment-emergent adverse events were identified.

The ACHIEVE trial also includes a REC, which is currently ongoing. The primary endpoint in the REC is the change from baseline in middle finger myotonia as measured by vHOT at 6 months compared to placebo, which is intended to serve as an intermediate clinical endpoint for U.S. Accelerated Approval. Secondary endpoints include change from baseline in splicing as measured by CASI-22, muscle strength as assessed by QMT, performance on both the 10MWR and 5xSTS, as well as the MDHI, all at 6 months compared to placebo. We intend that the data from the REC portion and ongoing long-term extension portions of the ACHIEVE trial will support a potential submission for U.S. Accelerated Approval.

The ACHIEVE REC is expected to enroll 60 patients at the 6.8 mg/kg Q8W. We expect to complete enrollment in the REC in the second quarter of 2026, with data from this cohort planned for the first quarter of 2027 and potential submission for U.S. Accelerated Approval planned for early in the third quarter of 2027.

We plan to initiate a global confirmatory Phase 3 clinical trial of z-basivarsen in March 2026, and we have aligned with the FDA on the Phase 3 trial design and protocol. We continue to pursue approval pathways for z-basivarsen outside of the United States. We anticipate a potential launch of z-basivarsen in the first quarter of 2028, assuming we receive favorable data, priority review is granted, and FDA approval is received on the anticipated timeline.

Facioscapulohumeral Dystrophy (FSHD)

Overview

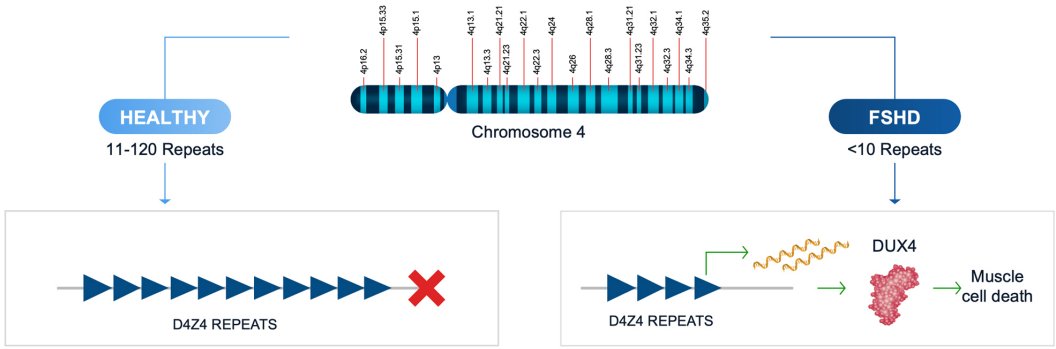
We are developing DYNE-302 to address the genetic basis of FSHD by reducing DUX4 expression in muscle tissue. In June 2024 and June 2025, we announced new preclinical data for DYNE-302, our product candidate for FSHD, that demonstrated robust and durable DUX4 suppression and functional benefit in a mouse model. We generated these data using an innovative hTfR1/iFLExD mouse model we developed that expresses TfR1 and enables tunable DUX4 induction in skeletal muscle. In hTfR1/iFLExD mice, a single intravenous dose of DYNE-302 resulted in dose-dependent and robust reduction of the DUX4 transcriptome that lasted up to three months, with benefit on muscle structure and function. DYNE-302 also demonstrated high in vitro potency in FSHD patient-derived myotubes. We are progressing DYNE-302 toward clinical development.

Disease overview and prevalence

FSHD is one of the most common muscular dystrophies and affects both sexes equally, with onset typically in teens and young adults. FSHD is characterized by progressive skeletal muscle loss that initially causes weakness in muscles in the face, shoulders, arms and trunk and progresses to weakness in muscles in lower extremities and the pelvic girdle. Skeletal muscle weakness results in significant physical limitations, including progressive loss of facial muscles that can cause an inability to smile or communicate, difficulty using arms for activities of daily living and difficulty getting out of bed, with many patients ultimately becoming dependent upon the use of a wheelchair for daily mobility activities. We estimate that the patient population is between 15,000 and 40,000 in the United States and approximately 20,000 to 50,000 in the European Union. We believe that there may be additional patients who are not formally diagnosed due to a perceived difficulty of obtaining a diagnosis and the fact that there are no approved treatments. Approximately two-thirds of cases are familial-inherited in an autosomal dominant fashion and one-third of cases occur randomly or as a result of environmental factors. FSHD affects all ethnic groups with similar incidence and prevalence.

FSHD is caused by aberrant expression of the DUX4 gene in muscle resulting in inappropriate presence of the DUX4 protein, a transcription factor causing the expression of other genes. Normally, DUX4-driven gene expression is limited to early embryonic development, after which time the DUX4 gene is silenced. In patients with FSHD, a genetic mutation causes expression of DUX4 protein to continue after embryonic development. The DUX4 protein regulates the expression of multiple genes encoding other proteins, some of which are toxic to muscle. Evidence of aberrant expression of DUX4 and the genes it activates, including ZSCAN4, MBD3L2, and TRIM43, is a major molecular signature that distinguishes muscles affected by FSHD from healthy muscle. The aberrant expression of DUX4 in FSHD results in muscle death and replacement by fat, which leads to the progressive muscle weakness and disability which characterize the disease, as shown in the figure below.

FSHD: genetic basis and disease process



Current approaches and limitations

There are currently no approved therapies for FSHD, and patients are treated with pain management and physical therapy. There are a number of product candidates in clinical development, including delpacibart braxlosiran, an antibody oligonucleotide conjugate which targets *DUX4* being evaluated in a Phase 3 clinical trial. To aid in the development of therapies for FSHD, we are sponsoring an ongoing natural history study seeking to validate new clinical outcome assessments and evaluate physiological biomarkers to support the design and implementation of future clinical trials.

Pompe Disease

Overview

We are developing DYNE-401 to deliver an enzyme replacement therapy to address the deficiency of the lysosomal enzyme, GAA that causes Pompe disease. We engineered FORCE-GAA by leveraging the FORCE platform and evaluated efficacy *in vivo* using hTfR1/6^{Neo} mice that were developed by crossing the well-established 6^{Neo} mouse model of Pompe with mice expressing human transferrin receptor 1. Using this approach, intravenous, or IV, administration cleared glycogen in muscle and the CNS and normalized lysosomal size in hTfR1/6^{Neo} mice. This approach reduced serum neurofilament light chain, a biomarker of axonal injury, providing evidence of benefit in the CNS and displayed superior dose potency compared to GAA alone. Additional data with this approach supported the potential for monthly dosing which is less frequent than approved enzyme replacement therapies for Pompe.

Disease overview and prevalence

Pompe disease is a rare, severe neuromuscular disorder caused by deficiency of GAA. Lack of GAA leads to glycogen accumulation and increase in lysosomal size in muscle and subsequent weakness, cardiomyopathy and respiratory failure. Enzyme replacement therapy with GAA is the standard of care and increases survival but has inadequate efficacy in skeletal muscle. Pompe is also characterized by CNS manifestations, including behavioral and cognitive deficits due to glycogen accumulation in CNS cells, which are not addressed by the standard of care therapy. We estimate that the patient population for Pompe is approximately 4,500 in the United States and 5,500 in the European Union.

Current approaches and limitations

There are three currently approved treatments for Pompe disease, all of which are enzyme replacement therapies that use recombinant human acid alpha glucosidase (rhGAA): Myozyme/Lumizyme (alglucosidase alfa), Nexviazyme/Nexviadyme (avalglucosidase alfa), and Pombiliti + Opfolda (cipaglucosidase alfa-atga in combination with miglustat). The first therapy approved, alglucosidase alfa, has improved the prognosis for Pompe disease patients. However, patients still experience disease progression and significant symptoms, largely attributed to poor delivery and uptake of the enzyme by skeletal muscle. Next-generation therapies, avalglucosidase alfa and the combination of cipaglucosidase alfa-atga with miglustat, were developed to enhance enzyme delivery and uptake by skeletal muscle. Both provide incrementally better clinical outcomes than alglucosidase alfa but failed to demonstrate superiority to alglucosidase alfa in Phase 3 trials, reflecting substantial remaining unmet medical need. Importantly, there is limited evidence that any of these three medicines penetrates the CNS, where Pompe symptoms include decreased processing speed, learning disabilities, and cognitive decline. Beyond these marketed products, the pipeline of drugs in development for the treatment of Pompe consists of early-stage product candidates that aim to address Pompe disease via alternative strategies, including improving muscle targeting of enzyme replacement therapy, reducing glycogen production and modifying liver or muscle cells to express GAA using gene therapy. There remains a high unmet medical need for new disease-modifying therapies for Pompe disease.

Discovery Programs and Pipeline Expansion Opportunities

We intend to expand our FORCE portfolio by pursuing programs in additional indications, including additional diseases involving the CNS, rare skeletal muscle diseases, as well as cardiac and metabolic muscle diseases. By rationally selecting therapeutic payloads to conjugate with our proprietary FORCE platform, we plan to develop product candidates to address the genetic basis of additional muscle diseases. For example, we plan to prioritize ASOs for indications driven by nuclear genetic targets and siRNAs for indications driven by cytoplasmic targets. We have completed screening and identified potent ASO and siRNA payloads against a number of cardiac and metabolic targets. We may selectively establish strategic collaborations for certain of these programs where we believe we could benefit from the resources or capabilities of other biopharmaceutical companies. We may also seek strategic collaborations where we believe we can utilize our FORCE platform to enhance delivery of third-party payloads to muscle tissue.

We have demonstrated in preclinical studies that the FORCE platform achieved delivery to the CNS. Intravenous, or IV, administration of FORCE conjugate, our proprietary Fab antibody conjugated to an ASO, achieved delivery to the CNS via TfR1 in both NHPs and our hTfR1/DMSXL mouse model. The hTfR1/DMSXL model that we developed expresses the human TfR1 and carries a human *DMPK* gene with more than 1,000 CTG repeats that represents a severe DM1 phenotype. In these studies, FORCE conjugate was generally well tolerated. In NHPs, FORCE conjugate achieved superior delivery compared to unconjugated ASO when both were administered intravenously. In addition, IV administration of FORCE in our preclinical studies showed broader distribution throughout the brain compared to intrathecal administration of unconjugated ASO. FORCE conjugate was also delivered to the brain of hTfR1/DMSXL mice and demonstrated robust knockdown of toxic human nuclear *DMPK* RNA and foci reduction in hTfR1/DMSXL mice.

Manufacturing

We do not own or operate manufacturing facilities. We currently rely on third-party contract manufacturing organizations, or CMOs, and suppliers for our Fab antibody, linkers and payloads that comprise our program candidates and the conjugation of these components. We plan to use third-party CMOs to support our IND-enabling studies and to fully supply our clinical trials and commercial activities but may also seek to eventually establish our own manufacturing facility for long-term commercial supply. As we scale manufacturing, we intend to continue to expand and strengthen our network of CMOs. We believe there are multiple sources for all of the materials required for the manufacture of our product candidates, as well as multiple CMOs who could assemble the antibody, linker and payload that comprise our program candidates.

Manufacturing is subject to extensive regulations that impose procedural and documentation requirements. These regulations govern record keeping, manufacturing processes and controls, personnel, quality control and quality assurance. Our CMOs are required to comply with these regulations and are assessed through regular monitoring and formal audits. Our third-party manufacturers are required to manufacture any product candidates we develop under current Good Manufacturing Practice, or cGMP, requirements and other applicable laws and regulations.

We have personnel with extensive technical, manufacturing, analytical and quality experience to oversee all contracted manufacturing and testing activities.

Intellectual property

We strive to protect our proprietary technology, inventions, improvements, platforms, program candidates, product candidates and components thereof, their methods of use and processes for their manufacture that we believe are important to our business, including by obtaining, maintaining, defending and enforcing patent and other intellectual property rights for the foregoing in the United States and in foreign jurisdictions. We also rely on trade secrets and confidentiality agreements to protect our confidential information and know-how and other aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our future commercial success depends in part on our ability to:

- obtain, maintain, enforce and defend patent and other intellectual property rights for our important technology, inventions and know-how;
- preserve the confidentiality of our trade secrets and other confidential information;
- obtain and maintain licenses to use and exploit intellectual property owned or controlled by third parties;
- operate without infringing, misappropriating or otherwise violating any valid and enforceable patents and other intellectual property rights of third parties; and

- defend against challenges and assertions by third parties challenging the validity or enforceability of our intellectual property rights, or our rights in our intellectual property, or asserting that the operation of our business infringes, misappropriates or otherwise violates their intellectual property rights.

As of December 31, 2025, we owned 70 patent application families related to our business, comprised of eleven U.S. provisional patent applications, 54 issued U.S. patents, 53 pending U.S. non-provisional patent applications, six pending Patent Cooperation Treaty, or PCT, patent applications, 472 pending foreign patent applications in Australia, Brazil, Canada, China, Europe, Eurasia, Hong Kong, India, Israel, Japan, Macau, South Korea, Mexico, New Zealand, Singapore, and South Africa, and fourteen granted foreign patents. We exclusively licensed one patent family, comprised of three issued U.S. patents, two pending U.S. patent applications and one issued European patent that has been validated in Belgium, Switzerland, Germany, Denmark, Spain, France, the United Kingdom, Ireland, Italy, the Netherlands and Sweden.

Our owned and licensed patent estate covers various aspects of our programs and technology, including our FORCE platform, proprietary antibodies, oligonucleotide conjugates, enzyme conjugates, methods of treatment and aspects of manufacturing. Any U.S. or foreign patents issued from national stage filings of our PCT patent applications and any U.S. patents issued from non-provisional applications we may file in connection with our provisional patent applications would be scheduled to expire on various dates from 2039 through 2046, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other governmental fees. Further details on certain segments of our patent portfolio are included below.

Additionally, in December 2025, for no monetary consideration, we entered into a global cross-license agreement with Avidity Biosciences, Inc., pursuant to which each party granted to the other a royalty-free, fully paid up, non-exclusive license with the right to sublicense, to certain of such party's patent rights for the development, testing, manufacture and commercialization of product candidates and programs in development.

FORCE platform

With regard to our FORCE platform, as of December 31, 2025, we owned three issued U.S. patents, nine pending U.S. non-provisional patent applications, and 71 pending foreign patent applications in Australia, Brazil, Canada, China, Europe, Eurasia, Hong Kong, India, Israel, Japan, Macau, South Korea, Mexico, Singapore, and South Africa. These applications relate to various aspects of our FORCE platform including proprietary antibodies, oligonucleotide conjugates, enzyme conjugates, methods of manufacture and methods of treatment. The three issued U.S. patents are expected to expire in 2042 without taking into account any possible patent term extensions. Any additional patents issued from these applications are expected to expire from 2039 to 2042; however, patent term extension may be available.

DMD programs (exons 51, 53, 45, 44, 55 and other)

With regard to our DMD programs, as of December 31, 2025, we owned 29 issued U.S. patents, 14 pending U.S. non-provisional patent applications, eight granted foreign patents and 170 pending foreign patent applications in Australia, Brazil, China, Canada, Europe, Eurasia, Hong Kong, India, Israel, Japan, South Korea, Mexico, Singapore, and South Africa. These patent filings relate to composition of matter and methods of treating disease involving our FORCE platform in the context of DMD. The 29 issued U.S. patents are expected to expire in 2039 and 2042 without taking into account any possible patent term extensions. The eight granted foreign patents are expected to expire in 2039-2041 without taking into account any possible patent term extensions. Any additional patents issued from these applications are expected to expire in 2039 and 2041 to 2044; however, patent term extension may be available.

DM1 program

With regard to our DM1 program, as of December 31, 2025, we owned one pending PCT patent application, 21 issued U.S. patents, ten pending U.S. non-provisional patent applications, ten granted foreign patents, and 102 pending foreign patent applications in Australia, Brazil, Canada, China, Europe, Eurasia, Hong Kong, India, Israel, Japan, South Korea, Mexico, New Zealand, Singapore, and South Africa. These applications relate to composition of matter and methods of treating disease involving our FORCE platform in the context of DM1. The 21 issued U.S. patents are expected to expire in 2039, 2042 and 2043 without taking into account any possible patent term extensions. The ten granted foreign patents are expected to expire in 2039-2041 without taking into account any possible patent term extensions. Any additional patents issued from these applications are expected to expire from 2039 to 2045; however, patent term extension may be available.

FSHD program

With regard to our FSHD program, as of December 31, 2025, we owned two pending PCT patent applications, 13 issued U.S. patents, one pending U.S. provisional patent application, eight pending U.S. non-provisional patent applications, five granted foreign patents and 73 pending foreign patent applications in Australia, Brazil, Canada, China, Europe, Eurasia, Hong Kong, India, Israel, Japan, South Korea, Mexico, Singapore, and South Africa. These patent filings relate to composition of matter and methods of treating disease involving our FORCE platform in the context of FSHD. The 13 issued U.S. patents are expected to expire in 2039 and 2042 without taking into account any possible patent term extensions. The five granted foreign patents are expected to expire in 2039 and 2041 without taking into account any possible patent term extensions. Any additional patents issued from these applications are expected to expire in 2039 and 2041 to 2046; however, patent term extension may be available. We also in-license a patent family from the University of Mons, or UMONS, comprising two pending U.S. patent applications. Any patents issued from these applications are expected to expire in 2031; however patent term extension may be available.

Pompe Program

With regard to our Pompe program, as of December 31, 2025, we owned one pending PCT patent application, two pending U.S. provisional patent applications, and eight pending foreign patent applications in Canada, China, Europe, Eurasia, Israel, Japan, South Korea, and South Africa. These patent filings relate to composition of matter and methods of treating disease involving our FORCE platform in the context of Pompe disease. Any patents issued from these applications are expected to expire in 2039, 2045, and 2046; however, patent term extension may be available.

Discovery programs

With regard to our discovery programs, as of December 31, 2025, we owned seven pending U.S. provisional patent applications, five pending U.S. non-provisional patent applications, and 24 pending foreign patent applications in Australia, Brazil, Canada, China, Europe, Eurasia, Hong Kong, India, Israel, Japan, South Korea, Mexico, Singapore, and South Africa. These applications relate to composition of matter and methods of treating disease involving our FORCE platform in the context of a variety of additional rare skeletal muscle diseases, as well as cardiac and metabolic muscle diseases and diseases involving the CNS. Any patents issued from these applications are expected to expire in 2039, 2041, 2042, and 2046; however, patent term extension may be available.

Patent prosecution

A PCT patent application is not eligible to become an issued patent until, among other things, we file one or more national stage patent applications in the jurisdictions in which we seek patent protection and do so within prescribed timelines of the PCT application’s priority date. These prescribed timelines are generally 30 months, 31 months or 32 months, depending on the jurisdiction. If we do not timely file any national stage patent applications, we may lose our priority date with respect to our PCT patent application and any potential patent protection on the inventions disclosed in such PCT patent application.

Moreover, a provisional patent application is not eligible to become an issued patent. A provisional patent application may serve as a priority filing for a non-provisional patent application we file within 12 months of such provisional patent application. If we do not timely file non-provisional patent applications, we may lose our priority date with respect to our existing provisional patent applications and any potential patent protection on the inventions disclosed in our provisional patent applications.

While we intend to timely file additional provisional patent applications and national stage and non-provisional patent applications relating to our PCT patent applications, we cannot predict whether any of our patent applications will result in the issuance of patents. If we do not successfully obtain patent protection, or if the scope of the patent protection we or our licensors obtain with respect to our product candidates or technology is insufficient, we will be unable to use patent protection to prevent others from using our technology or from developing or commercializing technology and products similar or identical to ours or other similar competing products and technologies. Our ability to stop third parties from making, using, selling, offering to sell, importing or otherwise commercializing any of our technology, inventions and improvements, either directly or indirectly, will depend in part on our success in obtaining, maintaining, defending and enforcing patent claims that cover our technology, inventions and improvements.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. The protection afforded by a patent varies on a product-by-product basis, from jurisdiction-to-jurisdiction, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of patent term adjustments and regulatory-related patent term extensions, the availability of legal remedies in a particular jurisdiction and the validity and enforceability of the patent. Patent laws and related enforcement in various jurisdictions outside of the United States are uncertain and may not protect our rights to the same extent as the laws of the United States. Changes in the patent laws and rules, whether by legislation, judicial decisions or regulatory interpretation, in the United States and other jurisdictions may have uncertain effects that could improve or diminish our ability to protect our inventions and obtain, maintain, defend and enforce our patent rights, and could therefore affect the value of our business in uncertain ways.

The area of patent and other intellectual property rights in biotechnology is evolving and has many risks and uncertainties, and third parties may have blocking patents and other intellectual property that could be used to prevent us from commercializing our platform and product candidates and practicing our proprietary technology. Our patent rights may be challenged, narrowed, circumvented, invalidated or ruled unenforceable, which could limit our ability to stop third parties from marketing and commercializing related platforms or product candidates or limit the term of patents that cover our platform and any product candidates. In addition, the rights granted under any issued patents may not provide us with protection or competitive advantages against third parties with similar technology, and third parties may independently develop similar technologies.

Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any competitive advantage provided by the patent. For this and other risks related to our proprietary technology, inventions, improvements, platforms and product candidates and intellectual property rights related to the foregoing, please see the section entitled “Risk factors—Risks related to our intellectual property.”

Patent term

The term of individual patents depends upon the laws of the jurisdictions in which they are obtained. In most jurisdictions in which we file, the patent term is 20 years from the earliest date of filing of the first non-provisional patent application to which the patent claims priority. However, the term of U.S. patents may be extended or adjusted for delays incurred due to compliance with FDA requirements or by delays encountered during prosecution that are caused by the United States Patent and Trademark Office, or the

USPTO. For example, in the United States, a patent claiming a new biologic product, its method of use or its method of manufacture may be eligible for a limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, for up to five years beyond the normal expiration date of the patent. Patent term extension cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date in the United States. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. During the period of extension, if granted, the scope of exclusivity is limited to the approved product for approved uses. Some foreign jurisdictions, including Europe and Japan, have analogous patent term extension provisions, which allow for extension of the term of a patent that covers a drug approved by the applicable foreign regulatory authority. For more information on patent term extensions, see Item 1. "Business—Government regulation—Patent term restoration and extension" in this Annual Report on Form 10-K. In the future, if and when any product candidates we may develop receive FDA approval, we expect to apply for patent term extensions on issued patents covering those product candidates. Moreover, we intend to seek patent term adjustments and extensions for any of our issued patents in any jurisdiction where such adjustments and extensions are available. However, there is no guarantee that the applicable authorities, including the USPTO and FDA, will agree with our assessment of whether such adjustments and extensions should be granted, and even if granted, the length of such adjustments and extensions.

Trade secrets

In addition to patent protection, we also rely on trade secrets, know-how, unpatented technology and other proprietary information to strengthen our competitive position. We currently, and may in the future continue to, rely on third parties to assist us in developing and manufacturing our products. Accordingly, we must, at times, share trade secrets, know-how, unpatented technology and other proprietary information, including those related to our platform, with them. We may in the future also enter into research and development collaborations with third parties that may require us to share trade secrets, know-how, unpatented technology and other proprietary information under the terms of research and development partnerships or similar agreements. Nonetheless, we take steps to protect and preserve our trade secrets and other confidential and proprietary information and prevent the unauthorized disclosure of the foregoing, including by entering into non-disclosure and invention assignment agreements with parties who have access to our trade secrets or other confidential and proprietary information, such as employees, consultants, outside scientific collaborators, contract research and manufacturing organizations, sponsored researchers and other advisors, at the commencement of their employment, consulting or other relationships with us. In addition, we take other appropriate precautions, such as maintaining physical security of our premises and physical and electronic security of our information technology systems, to guard against any misappropriation or unauthorized disclosure of our trade secrets and other confidential and proprietary information by third parties.

Despite these efforts, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or other confidential or proprietary information. In addition, we cannot provide any assurances that all of the foregoing non-disclosure and invention assignment agreements have been duly executed, and any of the counterparties to such agreements may breach them and disclose our trade secrets and other confidential and proprietary information. Although we have confidence in the measures we take to protect and preserve our trade secrets and other confidential and proprietary information, they may be inadequate, our agreements or security measures may be breached, and we may not have adequate remedies for such breaches. Moreover, to the extent that our employees, contractors, consultants, collaborators and advisors use intellectual property owned by others in their work for us, disputes may arise as to our rights in any know-how or inventions arising out of such work. For more information, please see the section entitled "Risk factors—Risks related to our intellectual property."

License agreement with the University of Mons

In April 2020, we entered into a license agreement with UMONS, or the UMONS Agreement, pursuant to which UMONS granted to us an exclusive, worldwide license to certain patents and patent applications related to oligonucleotides for our FSHD program and a non-exclusive, worldwide license to existing, related know-how. Each of the issued patents licensed to us under the UMONS Agreement is scheduled to expire in 2031. The licenses under the UMONS Agreement confer on us the right to research, develop and commercialize products, which we refer to as licensed products, and to practice processes, in each case, covered by the licensed patents and existing, related know-how.

Under the UMONS Agreement, we are obligated to use commercially reasonable efforts to develop at least one licensed product and, to the extent regulatory approval is obtained in such jurisdictions, to commercialize at least one licensed product in the United States and the United Kingdom or a member country of the European Union. Unless terminated earlier, the UMONS Agreement will remain in effect until the last to expire of the licensed patent rights on a licensed product-by-licensed product and country-by-country basis. UMONS may terminate the UMONS Agreement in the event of a material breach by us and our failure to cure such breach within a specified time period. We may voluntarily terminate the UMONS Agreement with prior notice to UMONS.

In connection with our entry into the UMONS Agreement, we paid UMONS an upfront payment of €50,000. We also agreed to make milestone payments to UMONS upon the achievement of specified development and regulatory milestones up to a maximum aggregate total of €400,000 for the first licensed product to achieve such milestones and up to a maximum aggregate total of €200,000 for each subsequent licensed product to achieve each such milestones, as well as a low single-digit percentage royalty on net sales of licensed products by us, our affiliates and sublicensees. These royalty obligations continue on a licensed product-by-licensed product and country-by-country basis until the expiration of the last licensed patent rights covering such licensed product in such country. In addition, if we sublicense rights under the UMONS Agreement, we are required to pay a low double-digit percentage of the sublicense revenue to UMONS. Additionally, if we choose to file, prosecute or maintain any patents included in the licensed patent rights under the UMONS Agreement, we will be required to bear the full cost and expenses of preparing, filing, prosecuting and maintaining any such patents.

Competition

The biotechnology and biopharmaceutical industries generally, and the muscle disease field specifically, are characterized by rapid evolution of technologies, sharp competition and strong defense of intellectual property. Any product candidates that we successfully develop and commercialize will have to compete with existing therapies and new therapies that may become available in the future. While we believe that our technology, development experience and scientific knowledge in the field of muscle diseases, oligonucleotide therapeutics and manufacturing provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions.

Currently, patients with DMD are treated with corticosteroids to manage the inflammatory component of the disease. EMFLAZA (deflazacort) is an FDA-approved corticosteroid marketed by PTC Therapeutics, Inc., or PTC. A novel steroid, AGAMREE (vamorolone) has been approved by the FDA for treatment of DMD in patients 2 years of age and older and is marketed by Catalyst Pharmaceuticals, Inc. Givinostat, a histone deacetylase, or HDAC, inhibitor, received FDA approval for treatment of DMD in patients 6 years of age and older and is marketed in the United States by ITF Therapeutics, LLC. In addition, there are four FDA-approved exon skipping drugs: EXONDYS 51 (eteplirsen), VYONDYS 53 (golodirsen) and AMONDYS 45 (casimersen), which are naked PMOs approved for the treatment of DMD patients amenable to exon 51, exon 53 and exon 45 skipping, respectively, and are marketed by Sarepta Therapeutics, Inc., or Sarepta, and VILTEPSO (vitolarsen), a naked PMO approved for the treatment of DMD patients amenable to exon 53 skipping, which is marketed by Nippon Shinyaku Co. Ltd. Additionally, there is one FDA-approved gene therapy for patients with a confirmed mutation in the

dystrophin gene, ELEVIDYS (delandistrogene moxeparvovec-rokl), which is marketed by Sarepta. Companies focused on developing treatments for DMD that target dystrophin mechanisms, as does our DMD program, include Wave Life Sciences Ltd. with WVE-N531, a stereopure oligonucleotide being evaluated in a Phase 2 clinical trial for patients amenable to exon 53 skipping; Entrada Therapeutics, Inc. with ENTR-601-44, an endosomal escape vehicle technology for the treatment of DMD patients amenable to exon 44 and exon 45 skipping respectively, currently being evaluated in Phase 1/2 clinical trials; BioMarin Pharmaceuticals, Inc. with BMN-351, an ASO for patients amenable to exon 51 skipping which is being evaluated in a Phase 1/2 clinical trial; SQY Therapeutics with SQY-51, a PMO for patients amenable to exon 51 skipping, which is also being evaluated in a Phase 1/2 clinical trial; NS Pharma, Inc. with NS-050/NCNP-03 and NS-089/NCNP-02, which are PMOs in Phase 1/2 and Phase 2 clinical trials for exon-50 and exon 44 skipping amenable DMD respectively; and Avidity with delpacibart zotadirsen (formerly known as AOC-1044), an antibody oligonucleotide conjugate for patients amenable to exon 44 skipping being evaluated in a Phase 1/2 clinical trial, which recently reported positive topline data and intent to file for accelerated approval with the FDA in 2026. In addition, gene therapies to treat DMD are in clinical development, including by Solid Biosciences Inc. (SGT-003), REGENXBIO Inc. (RGX-202), Genethon (GNT-0004), and Insmed (INS1201). Gene editing treatments that are in preclinical development are also being pursued by Vertex and Sarepta. We are also aware of several companies targeting non-dystrophin mechanisms for the treatment of DMD.

There are currently no approved therapies to treat the underlying cause of DM1. Product candidates currently in clinical development to treat DM1 include: tideglusib, a GSK3-ß inhibitor in late-stage clinical development by AMO Pharma Ltd. for children and adults with DM1; pitolisant, a selective histamine 3 receptor antagonist / inverse agonist being evaluated in a Phase 2 clinical trial for non-muscular symptoms of DM1 by Harmony Biosciences Holdings, Inc.; delpacibart etedesiran (formerly AOC-1001), an antibody-linked siRNA being evaluated in a Phase 3 clinical trial by Avidity Biosciences, Inc., or Avidity; PGN-EDODM1, a peptide-linked PMO currently being evaluated in a Phase 1 clinical trial by Pepgen, Inc.; ARO-DM1, a peptide-linked siRNA being evaluated in a Phase 1/2a clinical trial in Australia and New Zealand by Arrowhead Pharmaceuticals, Inc.; ATX-01, a lipophilic peptide conjugated anti-miR designed to target microRNA 23b currently being evaluated in a Phase 1/2 clinical trial by ARTHEx Biotech S.L.; VX-670, an endosomal escape vehicle technology with a CUG steric blocker oligonucleotide by Entrada Therapeutics, Inc. in collaboration with Vertex Pharmaceuticals Incorporated, or Vertex, being evaluated in a Phase 1/2 clinical trial in Canada, the United Kingdom, the European Union and Australia; SAR446268, an adeno-associated virus-, or AAV-, medicated gene therapy currently being evaluated in a Phase 1/2 clinical trial by Sanofi S.A., or Sanofi, in the United States and Argentina; and JUV-161, an AKT-signaling activator currently in a Phase 1 single-ascending dose clinical trial in healthy volunteers by Juvena Therapeutics Inc., or Juvena, in Australia.

There are currently no therapies approved to treat FSHD. Products currently in development for FSHD include: ARO-DUX4, an siRNA therapy being evaluated in a Phase 3 clinical trial and licensed by Arrowhead Pharmaceuticals, Inc. to Sarepta; delpacibart braxlosiran(formerly AOC-1020), an antibody oligonucleotide conjugate being evaluated in a Phase 1/2 clinical trial by Avidity and RO7204239, an anti-latent myostatin antibody by Roche Pharmaceuticals that is in a Phase 2 clinical trial. Satralizumab, an anti-IL-6 antibody, is being evaluated in a Phase 2 clinical trial by the University Hospital of Nice. EpiCrispr Biotechnologies is developing an AAV-delivered CRISPR epigenome modification therapy targeting DUX4 that is currently in Phase 1/2 clinical trials. Scholar Rock Holding Corporation cleared its IND application for apitegromab in FSHD with Phase 2 study initiation and patient dosing expected in mid-2026. Several other companies have therapies targeting DUX4 in preclinical development (e.g., Facio Biotherapies Pty Ltd, Kate Therapeutics Inc. (acquired by Novartis), Souffle Therapeutics, and Ionis Pharmaceuticals, Inc., or Ionis).

There are three currently approved medicines for Pompe disease, all of which are enzyme replacement therapies: Myozyme/Lumizyme (alglucosidase alfa) and Nexviazyme/Nexviadyme (avalglucosidase alfa) by Sanofi, and Pombiliti + Opfolda (cipaglucosidase alfa-atga in combination with miglustat) by Amicus Therapeutics, Inc. Beyond these marketed products, the Pompe clinical pipeline consists of several clinical-stage product candidates that aim to address Pompe disease via alternative strategies. ACTUS-101, a gene therapy delivered to the liver for continuous, endogenous production of GAA, is currently

being evaluated in a Phase 1/2 clinical trial by AskBio, Inc., or AskBio. AskBio, which is wholly owned by Bayer AG, also has its AB-1009 gene therapy program that is in a Phase 1/2 clinical trial in the United States for late-onset Pompe disease, or LOPD. AT-845 is a muscle-targeted gene therapy currently being evaluated in a Phase 1/2 clinical trial by Astellas Pharma US, Inc. for LOPD. In addition, ABX-1100 by ARO Biotherapeutics Co. and MZE-001 by Maze Therapeutics, Inc. are substrate reduction therapies in Phase 1 clinical trials. Denali Therapeutics, Inc. also announced plans to initiate a Phase 1 trial for its enzyme replacement therapy in January 2026.

We also expect to compete more generally with other companies developing alternative scientific and technological approaches to the treatment of muscle diseases, including other companies working to develop conjugates with oligonucleotides for extra-hepatic delivery, including Alnylam Pharmaceuticals, Inc., Aro Biotherapeutics, Inc., Arrowhead Pharmaceuticals, Inc., Avidity, Novo Nordisk A/S, DTx Pharma, Inc., Gennao Bio, Inc., Ionis and Sarepta, as well as gene therapy and gene editing approaches.

Many of our competitors, either independently or with strategic partners, have substantially greater financial, technical and human resources than we do. Accordingly, our competitors may be more successful than we are in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approval for treatments and achieving widespread market acceptance. Merger and acquisition activity in the biotechnology and biopharmaceutical industries may result in resources being concentrated among a smaller number of our competitors. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials and acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our commercial opportunity could be substantially limited if our competitors develop and commercialize products that are more effective, safer, less toxic, more convenient or less expensive than products we may develop. In geographies that are critical to our commercial success, competitors may also obtain regulatory approvals before us, resulting in our competitors building a strong market position in advance of the entry of our products. In addition, our ability to compete may be affected in many cases by insurers or other third-party payers seeking to encourage the use of other drugs. The key competitive factors affecting the success of all any products we may develop are likely to be their efficacy, safety, convenience, price and availability of reimbursement.

Government regulation

Government authorities in the United States, at the federal, state and local level and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, pricing, reimbursement, sales, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting and import and export of pharmaceutical products, including biological products. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources. The regulatory requirements applicable to product development, approval and marketing are subject to change, and regulations and administrative guidance often are revised or reinterpreted by government agencies in ways that may have a significant impact on our business.

Licensure and regulation of biologics in the United States

In the United States, any product candidates we may develop would be regulated as biological products, or biologics, under the Public Health Service Act, or PHSA, and the Federal Food, Drug and Cosmetic Act, or FDCA, and their implementing regulations and guidance.

A company, institution, or organization which takes responsibility for the initiation and management of a clinical development program for such products is referred to as a sponsor. A sponsor seeking approval

to market and distribute a new drug or biological product in the United States must typically secure the following:

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with the FDA's Good Laboratory Practices, or GLP, regulations and other applicable requirements;
- completion of the manufacture, under current Good Manufacturing Practice, or cGMP conditions, of the drug substance and drug product that the sponsor intends to use in human clinical trials along with required analytical and stability testing;
- design of a clinical protocol and submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety, potency and purity of the product candidate for each proposed indication, in accordance with current Good Clinical Practices, or GCP;
- preparation and submission to the FDA of a biologics license application, or BLA, for a biologic product candidate requesting marketing for one or more proposed indications, including submission of detailed information on the chemistry, manufacture and controls, or CMC, for the product candidate in clinical development and proposed labeling;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with current cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of any FDA audits of the preclinical studies and clinical trial sites to assure compliance with GLP, as applicable, and GCP, and the integrity of clinical data in support of the BLA;
- payment of application and program fees under the Prescription Drug User Fee Act, or PDUFA;
- securing FDA approval of the BLA and licensure of the new biologic product; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and any post-approval studies or other post-marketing commitments required by the FDA.

Preclinical studies and investigational new drug application

Before testing any biologic product candidate in humans, including an antibody, the product candidate must undergo preclinical testing. Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate the potential for efficacy and toxicity in animal studies. These studies are generally referred to as IND-enabling studies. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements, including GLP regulations and standards and the United States Department of Agriculture's Animal Welfare Act, if applicable.

With passage of the FDA's Modernization Act 2.0 in December 2022, Congress eliminated provisions in both the FDCA and the PHSA that required animal testing in support of a BLA. While animal testing may still be conducted, the FDA was authorized to rely on alternative non-clinical tests, including cell-based assays, microphysiological systems, or bioprinted or computer models. In April 2025, the FDA released a roadmap to replace animal testing in preclinical safety studies with scientifically validated new approach methodologies.

The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application.

An IND is an exemption from the FDCA that allows an unapproved product candidate to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer such investigational product to humans. The IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the product or conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks or concerns about the CMC for the product candidate. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trials can begin or recommence.

As a result, submission of the IND may result in the FDA not allowing the trials to commence or allowing the trial to commence on the terms originally specified by the sponsor in the IND. If the FDA raises concerns or questions either during this initial 30-day period, or at any time following the clearance of an IND, it may choose to impose a partial or complete clinical hold on the trial. Clinical holds are imposed by the FDA whenever there is concern for patient safety, which may be a result of new data, findings, or developments in clinical, preclinical and/or CMC or where there is non-compliance with regulatory requirements. This order issued by the FDA would delay either a proposed clinical trial or cause suspension of an ongoing trial, until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigations may proceed. This could cause significant delays or difficulties in completing our planned clinical trials or future clinical trials in a timely manner.

Expanded access to an investigational drug for treatment use

Expanded access, sometimes called “compassionate use,” is the use of investigational products outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options. The rules and regulations related to expanded access are intended to improve access to investigational products for patients who may benefit from investigational therapies. FDA regulations allow access to investigational products under an IND by the company or the treating physician for treatment purposes on a case-by-case basis for: individual patients (single-patient IND applications for treatment in emergency settings and non-emergency settings); intermediate-size patient populations; and larger populations for use of the investigational product under a treatment protocol or treatment IND application.

When considering an IND application for expanded access to an investigational product with the purpose of treating a patient or a group of patients, the sponsor and treating physicians or investigators will determine suitability when all of the following criteria apply: patient(s) have a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition; the potential patient benefit justifies the potential risks of the treatment and the potential risks are not unreasonable in the context or condition to be treated; and the expanded use of the investigational drug for the requested treatment will not interfere with initiation, conduct, or completion of clinical investigations that could support marketing approval of the product or otherwise compromise the potential development of the product.

There is no obligation for a sponsor to make its drug products available for expanded access. Drug and biologic companies must, however, make publicly available their policies for expanded access for individual patient access to products intended for serious diseases. Sponsors are required to make such policies publicly available upon the earlier of initiation of a Phase 2 or Phase 3 trial; or 15 days after the investigational drug or biologic receives designation as a breakthrough therapy, Fast Track product, or regenerative medicine advanced therapy.

In addition, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining

FDA permission under the FDA expanded access program. There is no obligation for a manufacturer to make its investigational products available to eligible patients as a result of the Right to Try Act.

Human clinical trials in support of a BLA

Clinical trials involve the administration of the investigational product candidate to healthy volunteers or patients with the disease or condition to be treated under the supervision of a qualified principal investigator in accordance with GCP requirements. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, inclusion and exclusion criteria, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

Further, each clinical trial must be reviewed and approved by an IRB either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors, the safety of human subjects, and the possible liability of the institution. An IRB must operate in compliance with FDA regulations. The FDA, IRB, or the clinical trial sponsor may suspend or discontinue a clinical trial at any time for various reasons, including a finding that the clinical trial is not being conducted in accordance with FDA requirements or that the participants are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP rules and the requirements for informed consent.

Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known either as a data monitoring committee, or DMC. This group may recommend continuation of the trial as planned, changes in trial conduct, or cessation of the trial at designated check points based on certain available data from the trial to which only the DMC has access. Finally, research activities involving infectious agents, hazardous chemicals, recombinant DNA and genetically altered organisms and agents may be subject to review and approval of an Institutional Biosafety Committee, or IBC, in accordance with NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may be required after approval.

- *Phase 1* clinical trials are initially conducted in a limited population to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics in healthy subjects or patients.
- *Phase 2* clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more costly Phase 3 clinical trials.
- *Phase 3* clinical trials proceed if the Phase 2 clinical trials demonstrate that a dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken within an expanded patient population to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites. A well-controlled, statistically robust Phase 3 trial may be designed to deliver the data that regulatory authorities will use to decide whether or not to approve, and, if approved, how to appropriately label a biologic; such Phase 3 studies are referred to as “pivotal.”

In some cases, the FDA may approve a BLA for a product but require the sponsor to conduct additional clinical trials to further assess the product’s safety and effectiveness after approval. Such trials are typically referred to as post-approval clinical trials. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of biologics approved under accelerated approval regulations. If the FDA approves a product

while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any post-approval clinical trial requirement or to request a change in the product labeling. The failure to exercise due diligence with regard to conducting post-approval clinical trials could result in withdrawal of approval for products.

A clinical trial may combine the elements of more than one phase and the FDA often requires more than one Phase 3 trial to support marketing approval of a product candidate. A company's designation of a clinical trial as being of a particular phase is not necessarily indicative that the study will be sufficient to satisfy the FDA requirements of that phase because this determination cannot be made until the protocol and data have been submitted to and reviewed by the FDA. Moreover, as noted above, a pivotal trial is a clinical trial that is believed to satisfy FDA requirements for the evaluation of a product candidate's safety and efficacy such that it can be used, alone or with other pivotal or non-pivotal trials, to support regulatory approval. Generally, pivotal trials are Phase 3 trials, but they may be Phase 2 trials if the design provides a well-controlled and reliable assessment of clinical benefit, particularly in an area of unmet medical need.

In December 2022, with the passage of Food and Drug Omnibus Reform Act, or FDORA, Congress required sponsors to develop and submit a diversity action plan for each Phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These diversity action plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. Specifically, diversity action plans must include the sponsor's goals for enrollment, the underlying rationale for those goals, and an explanation of how the sponsor intends to meet them. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for Diversity Action Plans, or DAPs. Unlike most guidance documents issued by the FDA, the DAP guidance when finalized will have the force of law because FDORA specifically dictates that the form and manner for submission of DAPs are specified in FDA guidance.

On January 27, 2025, in response to an Executive Order issued by President Trump on January 21, 2025, on Diversity, Equity and Inclusion programs, the FDA removed this draft guidance from its website. Subsequently, in July 2025, pursuant to a court order, the FDA restored the draft DAP guidance to its website with a statement that "information on this page may be modified and/or removed in the future subject to the terms of the court's order and implemented consistent with applicable law." In light of these ongoing actions, there is considerable uncertainty surrounding the draft DAP guidance and how the FDA will consider diversity action plans in connection with its review of new drug applications, or NDAs.

Additionally, in September 2025, the FDA issued final guidance with updated recommendations for GCPs aimed at modernizing the design and conduct of clinical trials. The updates are intended to help pave the way for more efficient clinical trials to facilitate the development of medical products. The final guidance is adopted from the International Council for Harmonisation's recently updated E6(R3) draft guideline that was developed to enable the incorporation of rapidly developing technological and methodological innovations into the clinical trial enterprise. In addition, the FDA issued final guidance outlining recommendations for the implementation of decentralized clinical trials.

In October 2025, the FDA issued final guidance that focuses on patient-focused drug development. The guidance outlines how stakeholders, such as patients, caregivers, researchers and medical product developers, can submit patient experience data in support of the development and approval of drug products. To that end, the guidance provides an overview of clinical outcome assessments, or COAs, in clinical trials, and the role that COAs may play in in evaluating the clinical benefit of a medical product.

Sponsors of clinical trials are required to register and disclose certain clinical trial information on a public registry (clinicaltrials.gov) maintained by the U.S. National Institutes of Health, or NIH. In particular, information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. The NIH's Final Rule on registration and reporting requirements for clinical trials became effective in 2017. Although the FDA has historically not enforced these reporting requirements, the FDA, as of January 31, 2026, has issued eight notices of non-compliance, thereby signaling the government's willingness to begin enforcing these requirements against non-compliant clinical trial sponsors. While these notices of

non-compliance did not result in civil monetary penalties, the failure to submit clinical trial information to clinicaltrials.gov, as required, is a prohibited act under the FDCA with violations subject to potential civil monetary penalties of up to $10,000 for each day the violation continues. Violations may also result in injunctions and/or criminal prosecution or disqualification from federal grants.

Interactions with the FDA During the Clinical Development Program

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Written IND safety reports must be promptly submitted to the FDA, the IRB and the investigators for serious and unexpected adverse events, any findings from other trials, in vivo laboratory tests or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. A development safety report detailing the results of the clinical trials must be submitted to the FDA on an annual basis.

In addition, sponsors are given opportunities to meet with the FDA at certain points in the clinical development program. Specifically, sponsors may meet with the FDA prior to the submission of an IND, or pre-IND application meeting, at the end of a Phase II clinical trial, or EOP2 meeting, and before a BLA is submitted, or pre-BLA meeting. Meetings at other times may also be requested. There are five types of meetings that occur between sponsors and the FDA. Type A meetings are those that are necessary for an otherwise stalled product development program to proceed or to address an important safety issue. Type B meetings include pre-IND application and pre-BLA meetings, as well as Type B end of phase meetings, such as EOP2 meetings. A Type C meeting is any meeting other than a Type A or Type B meeting regarding the development and review of a product. A Type D meeting is focused on a narrow set of issues (should be limited to no more than two focused topics) and should not require input from more than three disciplines or divisions. Finally, INTERACT meetings are intended for novel products and development programs that present unique challenges in the early development of an investigational product.

Clinical Studies Outside the United States in Support of FDA Approval

In connection with our clinical development program, we are conducting trials, and may conduct trials in the future, at sites outside the United States. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived. When a foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain regulatory requirements of the FDA in order to use the study as support for an IND or application for marketing approval. Specifically, the studies must be conducted in accordance with GCP, including undergoing review and receiving approval by an independent ethics committee, or IEC, and seeking and receiving informed consent from subjects. GCP requirements encompass both ethical and data integrity standards for clinical studies. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical studies, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign studies are conducted in a manner comparable to that required for IND studies.

The acceptance by the FDA of study data from clinical trials conducted outside the United States in support of U.S. approval may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted.

Pediatric Studies

Under the Pediatric Research Equity Act of 2003, a BLA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the sponsor plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The sponsor, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the sponsor may request an amendment to the plan at any time.

For products intended to treat a serious or life-threatening disease or condition, the FDA must, upon the request of a sponsor, meet to discuss preparation of the initial pediatric study plan or to discuss deferral or waiver of pediatric assessments. In addition, FDA will meet early in the development process to discuss pediatric study plans with sponsors and FDA must meet with sponsors by no later than the end-of-phase 1 meeting for serious or life-threatening diseases and by no later than 90 days after FDA's receipt of the study plan.

The FDA may, on its own initiative or at the request of the sponsor, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric trials begin. The law now requires the FDA to send a PREA Non-Compliance letter to sponsors who have failed to submit their pediatric assessments required under PREA, have failed to seek or obtain a deferral or deferral extension or have failed to request approval for a required pediatric formulation. It further requires the FDA to publicly post the PREA Non-Compliance letter and sponsor's response. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation, although FDA has recently taken steps to limit what it considers abuse of this statutory exemption. In May 2023, the FDA issued new draft guidance that further describes the pediatric study requirements under PREA.

Manufacturing and Compliance with cGMP requirements

Concurrent with clinical trials, companies usually complete additional preclinical studies and must also develop additional information about the physical characteristics of the biologic product candidate as well as finalize a process for manufacturing the product candidate in commercial quantities in accordance with cGMP requirements. To help reduce the risk of introduction of adventitious agents or of causing other adverse events with the use of biologic products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other requirements, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biologic product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biologic product candidate does not undergo unacceptable deterioration over its shelf life.

Manufacturers and others involved in the manufacture and distribution of products must also register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing

establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process. Any product manufactured by or imported from a facility that has not registered, whether foreign or domestic, is deemed misbranded under the FDCA. Establishments may be subject to periodic unannounced inspections by government authorities to ensure compliance with cGMPs and other laws. Inspections must follow a "risk-based schedule" that may result in certain establishments being inspected more frequently. Manufacturers may also have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting, or refusing inspection by the FDA may lead to a product being deemed to be adulterated.

The PREVENT Pandemics Act, enacted in December 2022, clarifies that foreign drug manufacturing establishments are subject to registration and listing requirements even if a drug or biologic undergoes further manufacture, preparation, propagation, compounding or processing at a separate establishment outside the United States prior to being imported or offered for import into the United States.

In May 2025, the FDA disclosed plans to expand its use of unannounced inspections of foreign manufacturing facilities that produce drugs and biologics distributed in the United States. Subsequently, in August 2025, the FDA introduced a "PreCheck" program with the intention of supporting companies as they build new facilities in the United States. The PreCheck program provides manufacturers with more frequent FDA communication at critical development stages, including facility design, construction, and pre-production. These FDA initiatives flow from an Executive Order issued by President Trump on May 5, 2025, calling for actions to reduce regulatory barriers to pharmaceutical manufacturing in the United States.

Submission and filing of a BLA

The results of product candidate development, preclinical testing and clinical trials, including negative or ambiguous results as well as positive findings, are submitted to the FDA as part of a BLA requesting license to market the product. The BLA must contain extensive manufacturing information and detailed information on the composition of the product and proposed labeling as well as payment of a user fee. Under federal law, the submission of most BLAs is subject to an application user fee, which for federal fiscal year 2026 is approximately $4.7 million for an application requiring clinical data. The sponsor of a licensed BLA is also subject to an annual program fee, which for federal fiscal year 2026 is approximately $0.4 million. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for products with orphan designation and a waiver for certain small businesses.

The FDA conducts a preliminary review of all applications within 60 days of receipt and must inform the sponsor at that time or before whether an application is sufficiently complete to permit substantive review. In pertinent part, FDA's regulations state that an application "shall not be considered as filed until all pertinent information and data have been received" by the FDA. In the event that FDA determines that an application does not satisfy this standard, it will issue a Refuse to File, or RTF, determination to the sponsor. The FDA may request additional information rather than accept an application for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing.

In October 2025, the FDA issued internal guidance clarifying that "materially incomplete or inadequately organized" applications that would not permit timely, efficient and complete review will be the subject of an RTF. The internal guidance also provides that the agency will issue an RTF for an application that relies on a single adequate and well-controlled investigation to support approval if prior communications with the FDA determined the need for more than one clinical study and any justification for a single investigation is inadequate.

Review and approval of a filed BLA

Once the submission of the BLA has been accepted for filing, the FDA begins an in-depth review of the application. Under the goals and policies agreed to by the FDA under the PDUFA, the FDA has ten months in which to complete its initial review of a standard application and respond to the sponsor, and

six months for a priority review of the application. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs. The review process may often be significantly extended by FDA requests for additional information or clarification. The review process and the PDUFA goal date may be extended by three months if the FDA requests or if the sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

In connection with its review of an application, the FDA typically will inspect the facility or facilities where the product candidate is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in full compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The PHSA emphasizes the importance of manufacturing control for products like biologics whose attributes cannot be precisely defined. Additionally, before approving an application, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. With passage of FDORA, Congress clarified the FDA's authority to conduct inspections by expressly permitting inspection of facilities involved in the preparation, conduct, or analysis of clinical and non-clinical studies submitted to the FDA as well as other persons holding study records or involved in the study process.

Moreover, the FDA will review a sponsor's financial relationship with the principal investigators who conducted the clinical trials in support of the BLA. That is because, under certain circumstances, principal investigators at a clinical trial site may also serve as scientific advisors or consultants to a sponsor and receive compensation in connection with such services. Depending on the level of that compensation and any other financial interest a principal investigator may have in a sponsor, the sponsor may be required to report these relationships to the FDA. The FDA will then evaluate that financial relationship and determine whether it creates a conflict of interest or otherwise affects the interpretation of the trial or the integrity of the data generated at the principal investigator's clinical trial site. If so, the FDA may exclude data from the clinical trial site in connection with its determination of safety and efficacy of the investigational product.

Under the PHSA, the FDA may approve a BLA if it determines that the product is safe, pure and potent, and the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure and potent. To reach this determination, the FDA must also conclude that the investigational product is effective and that its expected benefits outweigh its potential risks to patients. This "benefit-risk" assessment is informed by the extensive body of evidence about the product's safety, purity and potency in the BLA. This assessment is also informed by other factors, including: the severity of the underlying condition and how well patients' medical needs are addressed by currently available therapies; uncertainty about how the premarket clinical trial evidence will extrapolate to real-world use of the product in the post-market setting; and whether risk management tools are necessary to manage those specific risks.

On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities and any FDA audits of preclinical and clinical trial sites to assure compliance with GCPs, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. If the application is not approved, the FDA will issue a complete response letter, which will contain the conditions that must be met in order to secure final approval of the application, and when possible, will outline recommended actions the sponsor might take to obtain approval of the application.

Sponsors that receive a complete response letter may submit to the FDA information that represents a complete response to the issues identified by the FDA. Such resubmissions are classified under PDUFA as either Class 1 or Class 2. The classification of a resubmission is based on the information submitted by a sponsor in response to an action letter. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has two months to review a Class 1 resubmission and six months to review a Class 2 resubmission. The FDA will not approve an application until issues identified in the complete response letter have been addressed. While complete response letters, or CRLs, were previously treated by the

FDA as confidential and were only disclosed in action packages for approved products, the FDA announced in September 2025 that it will now release CRLs promptly after they are issued to sponsors. Since that announcement, the FDA has posted a number of CRLs on its website.

The FDA may also refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. In particular, the FDA may refer applications for novel biologic products or biologic products that present difficult questions of safety or efficacy to an advisory committee.

Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

If the FDA approves a new product, it may limit the approved indication(s) for use of the product. It may also require that contraindications, warnings, or precautions be included in the product labeling. In addition, the FDA may call for post-approval studies, including post-approval clinical trials, to further assess the product's efficacy and/or safety after approval. The agency may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patent registries. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track, breakthrough therapy, priority review and regenerative medicine advanced therapy designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are referred to as Fast Track designation, breakthrough therapy designation, priority review designation and regenerative medicine advanced therapy, or RMAT, designation. These designations are not mutually exclusive, and a product candidate may qualify for one or more of these programs. While these programs are intended to expedite product development and approval, they do not alter the standards for FDA approval.

Specifically, the FDA may designate a product for fast-track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast-track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast-track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast-track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast-track application does not begin until the last section of the application is submitted. In addition, the Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, in 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act. This law established a new regulatory scheme allowing for expedited review of products designated as "breakthrough therapies." A product may be designated as a breakthrough therapy if it is intended, either

alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner. Breakthrough designation may be rescinded if a product no longer meets the qualifying criteria.

Third, the FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months. Priority designation may be rescinded if a product no longer meets the qualifying criteria.

With passage of the Cures Act in December 2016, Congress authorized the FDA to accelerate review and approval of products designated as regenerative medicine advanced therapies. A product is eligible for RMAT designation if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product has the potential to address unmet medical needs for such disease or condition. The benefits of a regenerative medicine advanced therapy designation include early interactions with FDA to expedite development and review, benefits available to breakthrough therapies, potential eligibility for priority review, and accelerated approval based on surrogate or intermediate endpoints. RMAT designation may be rescinded if a product no longer meets the qualifying criteria.

On June 17, 2025, the FDA announced the creation of the Commissioner's National Priority Voucher, or CNPV, Program. Vouchers issued under this program can be redeemed by sponsors to shorten the review time of a BLA from approximately ten to twelve months to one to two months. The FDA has indicated that the CNPV Program will convene experts from the FDA's offices for a team-based review rather than using the standard review system. Clinical data will be reviewed by a multidisciplinary team of physicians and scientists who will pre-review the submitted information and convene for a one-day meeting. Vouchers under the CNPV Program will be given to companies aligned with U.S. national priorities.

In September 2025, the FDA introduced a framework intended to streamline the approval of new therapies for ultrarare diseases. The Rare Disease Evidence Principles is intended to allow sponsors to rely on a single-arm trial in support of approval of biologics that treat rare diseases with very small patient populations and where the disease is linked to a known genetic defect and characterized by progressive functional deterioration leading to disability or death in a short period of time. The targeted diseases should also lack adequate alternative therapies.

Accelerated approval pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of

alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a product, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, confirm a clinical benefit during post-marketing studies or dissemination of false or misleading promotional materials would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

With passage of FDORA in December 2022, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation authorized the FDA to: require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded, require a sponsor of a product granted accelerated approval to submit progress reports on its post-approval studies to the FDA every six months (until the study is completed); and use expedited procedures to withdraw accelerated approval of an NDA or BLA after the confirmatory trial fails to verify the product's clinical benefit. Further, FDORA requires the FDA to publish on its website "the rationale for why a post-approval study is not appropriate or necessary" whenever it decides not to require such a study upon granting accelerated approval.

In March 2023, the FDA issued draft guidance that outlines its current thinking and approach to accelerated approval. The FDA indicated that the accelerated approval pathway is commonly used for approval of oncology drugs due to the serious and life-threatening nature of cancer. Although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach as it provides a more robust efficacy and safety assessment and allows for direct comparisons to an available therapy. Subsequently, in December 2024 and January 2025, the FDA issued additional draft guidance relating to accelerated approval. This guidance describes FDA's latest thinking on what it means to conduct a confirmatory trial with due diligence and how the FDA plans to interpret whether such a study needs to be underway at the time of approval. While this guidance currently only in draft form and will ultimately not be legally binding even when finalized, sponsors typically observe the FDA's guidance closely to ensure that their investigational products qualify for accelerated approval.

Post-approval regulation

If regulatory approval for marketing of a product or new indication for an existing product is obtained, the sponsor will be required to comply with all regular post-approval regulatory requirements as well as any post-approval requirements that the FDA have imposed as part of the approval process. The sponsor will be required to report certain adverse reactions and production problems to the FDA, provide updated safety, potency and purity information and comply with requirements concerning advertising and promotional labeling requirements. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP regulations, which impose certain procedural and documentation requirements upon manufacturers. Accordingly, the sponsor and its third-party manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMP regulations and other regulatory requirements.

A product may also be subject to official lot release, meaning that the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official lot release, the manufacturer must submit samples of each lot, together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot, to the FDA. The FDA may in addition perform certain confirmatory tests on lots of some products before releasing the lots for distribution. Finally, the FDA will conduct laboratory research related to the safety, purity, potency and effectiveness of pharmaceutical products.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post- market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product recall, seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

Pharmaceutical products may be promoted only for the approved indications and in accordance with the provisions of the approved label. Although healthcare providers may prescribe products for uses not described in the drug's labeling, known as off-label uses, in their professional judgment, drug manufacturers are prohibited from soliciting, encouraging or promoting unapproved uses of a product. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. In September 2021, the FDA published final regulations which describe the types of evidence that the agency will consider in determining the intended use of a biologic.

It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in nonpromotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information. Moreover, with the passage of the Pre-Approval Information Exchange Act in December 2022, sponsors of products that have not been approved may proactively communicate to payors certain information about products in development to help expedite patient access upon product approval. Previously, such communications were permitted under FDA guidance but

the new legislation explicitly provides protection to sponsors who convey certain information about products in development to payors, including unapproved uses of approved products.

Additionally, in January 2025, the FDA published final guidance outlining its policies governing the distribution of scientific information to healthcare providers about unapproved uses of approved products. The final guidance calls for such communications to be truthful, non-misleading and scientifically sound and to include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use. If a company engages in such communications consistent with the guidance's recommendations, the FDA indicated that it will not treat such communications as evidence of unlawful promotion of a new intended use for the approved product. While this guidance only applies to communications about unapproved uses of approved products, it may be helpful in understanding the FDA's approach to communications about unapproved products.

If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the DOJ, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Orphan drug designation

Orphan drug designation in the United States is designed to encourage sponsors to develop products intended for treatment of rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available the biologic for the disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation qualifies a company for tax credits and market exclusivity for seven years following the date of the product's marketing approval if granted by the FDA. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. A product becomes an orphan when it receives orphan drug designation from the Office of Orphan Products Development at the FDA based on acceptable confidential requests made under the regulatory provisions. The product must then go through the review and approval process like any other product.

A sponsor may request orphan drug designation of a previously unapproved product or new orphan indication for an already marketed product. In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first drug. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation.

If a product with orphan designation receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will receive orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve another sponsor's marketing application for the same product for the same indication for seven years, except in certain limited circumstances. If a product designated as an orphan drug ultimately receives marketing approval for an indication broader than what was designated in its orphan drug application, it may not be entitled to exclusivity.

Orphan drug exclusivity will not bar approval of another product under certain circumstances, including if the company with orphan drug exclusivity is not able to meet market demand or the subsequent product is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care. This is the case despite an earlier court opinion holding that the Orphan Drug Act unambiguously required the FDA to recognize orphan drug exclusivity regardless of a showing of clinical superiority. Under legislation passed in 2020, the requirement for a product to show clinical superiority applies to drug products that received orphan drug designation before enactment of amendments to the FDCA in 2017 but have not yet been approved by FDA.

In September 2021, the Court of Appeals for the 11th Circuit held that, for the purpose of determining the scope of market exclusivity, the term “same disease or condition” in the statute means the designated “rare disease or condition” and could not be interpreted by the FDA to mean the “indication or use.” Thus, the court concluded, orphan drug exclusivity applies to the entire designated disease or condition rather than the “indication or use.” Although there have been legislative proposals to overrule this decision, they have not been enacted into law. On January 23, 2023, the FDA announced that, in matters beyond the scope of the court’s order, the FDA will continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug was approved. More recently however, on February 14, 2025, a federal district court in Washington, D.C. fully embraced the reasoning of the *Catalyst* decision in another decision challenging the scope of orphan drug exclusivity. On April 17, 2025, the FDA appealed this decision to the U.S. Court of Appeals for the D.C. Circuit. The implications of this decision, and its impact on the FDA’s implementation of the Orphan Drug Act, are unclear at this point.

Pediatric exclusivity

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of regulatory exclusivity to the term of any existing regulatory exclusivity, including orphan exclusivity. This six-month exclusivity may be granted if a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA’s request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity that cover the product are extended by six months.

Biosimilars and exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively, the ACA, which was signed into law in March 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA. The BPCIA established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. A biosimilar is a biological product that is highly similar to an existing FDA-licensed “reference product.” To date, the FDA has approved a number of biosimilars and the first interchangeable biosimilar product was approved on July 30, 2021 and a second product previously approved as a biosimilar was designated as interchangeable in October 2021. The FDA has also issued numerous guidance documents outlining its approach to reviewing and licensing biosimilars and interchangeable biosimilars under the PHSA.

Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is “biosimilar to” or “interchangeable with” a previously approved biological product or “reference product.” In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. In December 2022, Congress clarified through FDORA that the FDA may approve multiple first interchangeable biosimilar

biological products so long as the products are all approved on the first day on which such a product is approved as interchangeable with the reference product.

An application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products.
There have been government proposals to reduce the 12-year reference product exclusivity period, but none has been enacted to date. At the same time, since passage of the BPCIA, many states have passed laws or amendments to laws, which address pharmacy practices involving biosimilar and interchangeable biosimilar products.

Further, the FDA may revise the standards governing approval of biosimilars so as to bring such products to the market more quickly. For example, in October 2025, the FDA issued draft guidance which proposes to eliminate the need for sponsors of biosimilar products to conduct comparative human clinical efficacy studies, allowing them to rely instead on analytical testing to demonstrate product differences from a reference product.

Federal and state data privacy and security laws

There are multiple privacy and data security laws that may impact our business activities, in the United States and in other countries where we conduct trials or where we may do business in the future. These laws are evolving and may increase both our obligations and our regulatory risks in the future. In the health care industry, generally, under the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, the U.S. Department of Health and Human Services, or HHS, has issued regulations to protect the privacy and security of protected health information, or PHI, used or disclosed by covered entities including certain healthcare providers, health plans and healthcare clearinghouses. HIPAA also regulates standardization of data content, codes and formats used in healthcare transactions and standardization of identifiers for health plans and providers. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 or HITECH, and their regulations, including the final omnibus rule published on January 25, 2013, also imposes certain obligations on the business associates of covered entities and their subcontractors that obtain protected health information in providing services to or on behalf of covered entities. HIPAA may apply to us in certain circumstances and may also apply to our business partners in ways that may impact our relationships with them. Our clinical trials are regulated by the "common rule," which also includes specific privacy-related provisions. In addition to federal privacy regulations, there are a number of state laws governing confidentiality and security of health information that are applicable to our business. In addition to possible federal administrative, civil and criminal penalties for HIPAA violations, state attorneys general are authorized to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. Accordingly, state attorneys general have brought civil actions seeking injunctions and damages resulting from alleged violations of HIPAA's privacy and security rules. State attorneys general also have authority to enforce state privacy and security laws. New laws and regulations governing privacy and security may be adopted in the future as well.

In 2018, California passed into law the California Consumer Privacy Act, or the CCPA, which took effect on January 1, 2020 and imposed many requirements on businesses that process the personal information of California residents. Many of the CCPA's requirements are similar to those found in the General Data Protection Regulation, or GDPR, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of "sales" of their personal information. The CCPA contains significant penalties for companies that violate its requirements. In November 2020, California voters passed a ballot initiative for the

California Privacy Rights Act, or the CPRA, which went into effect on January 1, 2023 and significantly expanded the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also created a new enforcement agency – the California Privacy Protection Agency – whose sole responsibility is to enforce the CPRA, which will further increase compliance risk. The provisions in the CPRA may apply to some of our business activities.

In addition to California, a number of other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect over the next few years. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of "sensitive" data, which includes health data in some cases. Some of the provisions of these laws may apply to our business activities. There are also states that are strongly considering or have already passed comprehensive privacy laws during the 2024 legislative sessions that went into effect in 2025. Other states will be considering similar laws in the future, and Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. For example, the State of Washington passed the My Health My Data Act in 2023 which specifically regulated health information that is not otherwise regulated by the HIPAA rules, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data, and more states are considering such legislation in 2024. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Plaintiffs' lawyers are also increasingly using privacy-related statutes at both the state and federal level to bring lawsuits against companies for their data-related practices. In particular, there have been a significant number of cases filed against companies for their use of pixels and other web trackers. These cases often allege violations of the California Invasion of Privacy Act and other state laws regulating wiretapping, as well as the federal Video Privacy Protection Act.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our current or future business activities, including certain clinical research, sales and marketing practices and the provision of certain items and services to our customers, could be subject to challenge under one or more of such privacy and data security laws. The heightening compliance environment and the need to build and maintain robust and secure systems to comply with different privacy compliance and/or reporting requirements in multiple jurisdictions could increase the possibility that a healthcare company may fail to comply fully with one or more of these requirements. If our operations are found to be in violation of any of the privacy or data security laws or regulations described above that are applicable to us, or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal, civil and administrative penalties, damages, fines, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a consent decree or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any product candidates we may develop, once approved, are sold in a foreign country, we may be subject to similar foreign laws.

Patent term restoration and extension

In the United States, a patent claiming a new biologic product, its method of use or its method of manufacture may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent extension of up to five years for patent term lost during product development and FDA regulatory review. Assuming grant of the patent for which the extension is sought, the restoration period for a patent covering a product is typically one-half the time between the effective date of the IND involving human beings and the submission date of the BLA, plus the time between the submission date

of the BLA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date in the United States. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension in consultation with the FDA.

Regulation and procedures governing approval of medicinal products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, a sponsor will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the European Union generally follows the same lines as in the United States. It entails satisfactory completion of preclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication. It also requires the submission to the relevant competent authorities of a marketing authorization application, or MAA, and granting of a marketing authorization by these authorities before the product can be marketed and sold in the European Union.

Non-clinical studies

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with the principles of good laboratory practice, or EU GLP, as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products – e.g., radio-pharmaceutical precursors for radio-labeling purposes). In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the EU GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These EU GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trial approval

On January 31, 2022, the new Clinical Trials Regulation (EU) No 536/2014, or CTR became effective in the European Union and replaced the prior Clinical Trials Directive 2001/20/EC. The new regulation aims at simplifying and streamlining the authorization, conduct and transparency of clinical trials in the European Union. Under the new coordinated procedure for the approval of clinical trials, the sponsor of a clinical trial to be conducted in more than one Member State of the European Union, or EU Member State, will only be required to submit a single application for approval. The submission will be made through the Clinical Trials Information System, a new clinical trials portal overseen by the EMA and available to clinical trial sponsors, competent authorities of the EU Member States and the public. All clinical trials in the European Union (including those which are ongoing) are subject to the CTR.

Beyond streamlining the process, the CTR includes a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors, and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (EU Member States concerned). Part II is assessed separately by each EU Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the CTR.

The CTR did not change the preexisting requirement that a sponsor must obtain prior approval from the competent national authority of the EU Member State in which the clinical trial is to be conducted. If the clinical trial is conducted in different EU Member States, the competent authorities in each of these EU Member States must provide their approval for the conduct of the clinical trial. Furthermore, the sponsor may only start a clinical trial at a specific study site after the applicable ethics committee has issued a favorable opinion.

Parties conducting certain clinical trials must, as in the United States, post clinical trial information in the EU at the EU Clinical Trials Register (https://eudract.ema.europa.eu).

PRIME designation in the European Union

In March 2016, the EMA launched an initiative to facilitate development of product candidates in indications, which are often rare, for which few or no therapies currently exist. The PRIority MEdicines, or PRIME, scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. Products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated MAA assessment once a dossier has been submitted. Importantly, a dedicated EMA contact and rapporteur from the CHMP or Committee for Advanced Therapies, are appointed early in the PRIME scheme facilitating increased understanding of the product at the EMA's Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

Marketing authorization

To obtain a marketing authorization for a product under the European Union regulatory system, a sponsor must submit an MAA either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in EU Member States (decentralized procedure, national procedure, or mutual recognition procedure). A marketing authorization may be granted only to a sponsor established in the European Union. Regulation (EC) No 1901/2006 provides that prior to obtaining a marketing authorization in the European Union, a sponsor must demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, class waiver or a deferral for one or more of the measures included in the PIP.

The centralized procedure provides for the grant of a single MAA by the European Commission, or EC, that is valid for all EU Member States. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional. Manufacturers must demonstrate the quality, safety and efficacy of their products to the EMA, which provides an opinion regarding the MAA. The EC grants or refuses marketing authorization in light of the opinion delivered by the EMA.

Under the centralized procedure, the CHMP established at the EMA is responsible for conducting an initial assessment of a product. Under the centralized procedure in the EU, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the sponsor in response to questions of the CHMP. Accelerated evaluation with a time limit of 150 days may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days, but it is possible that the CHMP may revert to the standard time limit for the

centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment.

The decentralized procedure provides for approval by one or more other concerned EU Member States of an assessment of an application for marketing authorization conducted by one EU Member State, known as the reference EU Member State. In accordance with this procedure, a sponsor submits an application for marketing authorization to the reference EU Member State and the concerned EU Member States. On the basis of its review, the CHMP provides a scientific opinion on whether or not an MAA should be granted for a product candidate. Within 15 calendar days of receipt of a final opinion from the CHMP, the EC must prepare a draft decision concerning an MAA. This draft decision must take the CHMP opinion and any relevant provisions of EU law into account. Before arriving at a final decision, the EC must consult the Standing Committee on Medicinal Products for Human Use. This committee is composed of representatives of the EU Member States and is chaired by a non-voting EC representative. The decentralized marketing authorization procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product candidate is applying to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States which, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If the relevant EU Member State cannot approve the reference EU Member State's assessment report due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the EC, whose decision is binding on all EU Member States.

Conditional marketing authorization

In specific circumstances, EU legislation on Conditional Marketing Authorizations for Medicinal Products for Human Use, or conditional marketing authorization, enables sponsors to obtain a conditional marketing authorization prior to obtaining the comprehensive clinical data required for an MAA under Article 14-a of Regulation (EC) No 726/2004. Such conditional approvals may be granted for product candidates (including medicines designated as orphan medicinal products) if: (1) the risk-benefit balance of the product candidate is positive, (2) it is likely that the sponsor will be in a position to provide the required comprehensive clinical trial data, (3) the product fulfills unmet medical needs and (4) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization.

Exceptional Circumstances

A marketing authorization may also be granted "under exceptional circumstances" when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. This may arise in particular when the intended indications are very rare and, in the present state of scientific knowledge, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. This marketing authorization is close to the conditional marketing authorization as it is reserved to medicinal products to be approved for severe diseases or unmet medical needs and the applicant does not hold the complete data set legally required for the grant of a marketing authorization. However, unlike the conditional marketing authorization, the applicant does not have to provide the missing data and will never have to. Although the marketing authorization "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the marketing authorization is withdrawn in case the

risk-benefit ratio is no longer favorable. Under these procedures, before granting the marketing authorization, the EMA or the competent authorities of the member states make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety, and efficacy. Except conditional marketing authorizations, marketing authorizations have an initial duration of five years. After these five years, the authorization may be renewed on the basis of a reevaluation of the risk-benefit balance.

Regulatory data protection in the European Union

In the EU, new chemical entities approved on the basis of a complete independent data package qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity pursuant to Regulation (EC) No 726/2004, as amended, and Directive 2001/83/EC, as amended. Data exclusivity prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic (abbreviated) application for a period of eight years. During the additional two-year period of market exclusivity, a generic MAA can be submitted, and the innovator's data may be referenced, but no generic medicinal product can be marketed until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, is held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity so that the innovator gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained marketing authorization based on an MAA with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials.

In November 2020, the EC launched a review of the EU's pharmaceutical legislation, including its provisions governing regulatory exclusivity. The EC's proposal for revision of several legislative instruments related to medicinal products was published in April 2023 and includes, among other things, provisions that would potentially reduce the duration of regulatory data protection. On December 11, 2025, the European Parliament and Council reached a provisional political agreement on the legislation, which is expected to be adopted by mid-2026. Key changes include updating regulatory exclusivity to a new system with eight years of data exclusivity and a reduced market exclusivity period to one year, which can be extended if specific conditions are fulfilled up to a maximum of eleven years. This measure, and others, are expected to be adopted by mid-2026 and, following a transition period of 24 months, will likely take effect in mid-2028.

Patent term extensions in the European Union and other jurisdictions

The European Union also provides for patent term extension through Supplementary Protection Certificates, or SPCs. The rules and requirements for obtaining a SPC are similar to those in the United States. An SPC may extend the term of a patent for up to five years after its originally scheduled expiration date and can provide up to a maximum of fifteen years of marketing exclusivity for a drug. In certain circumstances, these periods may be extended for six additional months if pediatric exclusivity is obtained. Although SPCs are available throughout the European Union, sponsors must apply on a country-by-country basis. Similar patent term extension rights exist in certain other foreign jurisdictions outside the European Union.

Periods of authorization and renewals

An MAA is valid for five years, in principle, and it may be renewed after five years on the basis of a reevaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To that end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the EC or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not

followed by the placement of the drug on the EU market (in the case of the centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid.

Regulatory requirements after marketing authorization

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product. These include compliance with the EU's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. In addition, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the EMA's GMP requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in manufacturing, processing and packing of drugs to assure their safety and identity. Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union under Directive 2001/83EC, as amended. At the same time, the marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union under Directive 2001/83EC, as amended, and are also subject to EU Member State laws. Direct-to-consumer advertising of prescription medicines is prohibited across the European Union.

Orphan drug designation and exclusivity

Regulation (EC) No 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan drug by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (1) a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Union when the application is made, or (2) a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment. For either of these conditions, the sponsor must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the drug will be of significant benefit to those affected by that condition.

An orphan drug designation provides a number of benefits, including fee reductions, regulatory assistance and the possibility to apply for a centralized EU marketing authorization. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. During this market exclusivity period, neither the EMA nor the EC or the member states can accept an application or grant a marketing authorization for a "similar medicinal product." A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation because, for example, the product is sufficiently profitable not to justify market exclusivity.

Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals, and these efforts could continue as countries attempt to manage health care expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on health care costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States, and parallel trade, such as arbitrage between low-priced and high-priced EU Member States, can further reduce prices.

Brexit and the regulatory framework in the United Kingdom

The United Kingdom's withdrawal from the EU took place on January 31, 2020. The EU and the United Kingdom reached an agreement on their new partnership in the Trade and Cooperation Agreement, entered into force on May 1, 2021. As of January 1, 2025, the Medicines and Healthcare Products Regulatory Agency, or the MHRA, is responsible for approving all medicinal products destined for the U.K. market (i.e., Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland.

The MHRA relies on the Human Medicines Regulations 2012 (SI 2012/1916) (as amended), or the HMR, as the primary basis of regulating medicines. The HMR has incorporated into the domestic law the body of EU law instruments governing medicinal products that pre-existed prior to the U.K.'s withdrawal from the European Union. In April 2025, the U.K. Parliament adopted amendments to improve and strengthen the clinical trials regulatory regime in the United Kingdom. These revisions will take effect on April 28, 2026, and were needed to replace the prior requirements in the United Kingdom. that were based on the repealed EU Clinical Trials Directive (2001/20/EC), which has been replaced by the CTR.

As of January 1, 2024 on, a new international recognition procedure, or IRP, applies in the United Kingdom and is intended to facilitate approval of pharmaceutical products in the United Kingdom. The IRP is open to applicants that have already received an authorization for the same product from one of the MHRA's specified Reference Regulators, or RRs. The RRs notably include EMA and regulators in the EEA member states for approvals in the EU centralized procedure and mutual recognition procedure as well as the FDA (for product approvals granted in the United States). The RR assessment must have undergone a full and standalone review. RR assessments based on reliance or recognition cannot be used to support an IRP application. A CHMP positive opinion or a Mutual Recognition and Decentralised Procedure positive end of procedure outcome is an RR authorization for the purposes of IRP.

Furthermore, the EU General Data Protection Regulation, or GDPR, continues to apply in the United Kingdom in substantially unvaried form under the UK GDPR and is complemented by the U.K. Data Protection Act of 2018, which achieved Royal Assent on May 23, 2018 and remains effective in the United Kingdom in amended form. The United Kingdom has already determined that it considers all of the EU Member States and EEA member states to be adequate for the purposes of data protection, ensuring that data flows from the United Kingdom to the EU/EEA remain unaffected. In addition, a recent decision from the EC appears to deem the United Kingdom as being "essentially adequate" for purposes of data transfer from the European Union to the United Kingdom. On December 19, 2025, the EC renewed this decision until December 27, 2031. The United Kingdom and the United States have also agreed to a U.S.- U.K. "Data Bridge," which functions similarly to the EU-U.S. Data Privacy Framework and provides an additional legal mechanism for companies to transfer personal data from the United Kingdom to the United States.

General Data Protection Regulation

The collection, use, disclosure, transfer or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR is a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance.

In October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which would legitimize the transfer of personal data from the European Union to the United States. The EC initiated the process to adopt an adequacy decision for the EU-U.S. Data Privacy Framework in December 2022 and adopted that decision on July 10, 2023. The adequacy decision permits U.S. companies who self-certify to the EU-U.S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the European Union to the United States. However, some privacy advocacy groups have already suggested that they will be challenging the EU-U.S. Data Privacy Framework. If these challenges are successful, they may not only impact the EU-U.S. Data Privacy Framework, but also further limit the viability of the standard contractual clauses and other data transfer mechanisms. The uncertainty around this issue has the potential to impact our business operations in the European Union.

For more information on these matters and the GDPR, please see the section entitled “Risk Factors—Risks related to regulatory approval and other regulatory and legal compliance matters—We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies, contractual obligations and failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition, results of operations or prospects.”

Coverage, pricing and reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may seek regulatory approval by the FDA or other government authorities. In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payers to reimburse all or part of the associated healthcare costs. Patients are unlikely to use any product candidates we may develop unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such product candidates. Even if any product candidates we may develop are approved, sales of such product candidates will depend, in part, on the extent to which third-party payers, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage and establish adequate reimbursement levels for, such product candidates. The process for determining whether a payer will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payer will pay for the product once coverage is approved. Third-party payers are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payers may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable marketing approvals. Nonetheless, product candidates may not be considered medically necessary or cost-effective. A decision by a third-party payer not to cover any product candidates we may develop could reduce physician utilization of such product candidates once approved and have a material adverse effect on our sales, results of operations and financial condition. Additionally, a payer’s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payer’s determination to provide coverage for a product does not assure that other payers will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payer to payer. Third-party reimbursement and coverage may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. In addition, any companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion

pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to any companion diagnostics.

The containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of pharmaceuticals have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

If we obtain approval in the future to market in the United States any product candidates we may develop, we may be required to provide discounts or rebates under government healthcare programs or to certain government and private purchasers in order to obtain coverage under federal healthcare programs such as Medicaid. Participation in such programs may require us to track and report certain drug prices. We may be subject to fines and other penalties if we fail to report such prices accurately.

Outside the United States, ensuring adequate coverage and payment for any product candidates we may develop will face challenges. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the cost-effectiveness of any product candidates we may develop to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our commercialization efforts.

In the EU, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies (so called health technology assessments) in order to obtain reimbursement or pricing approval. For example, the EU provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU member states may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the EU have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the EU. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states, and parallel trade (arbitrage between low-priced and high-priced member states), can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries.

Healthcare law and regulation

Healthcare providers and third-party payers play a primary role in the recommendation and prescription of pharmaceutical products that are granted marketing approval. Arrangements with providers, consultants, third-party payers and customers are subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, laws governing the reporting of payments to physicians and teaching hospitals, patient privacy laws and regulations and other healthcare laws and regulations that may constrain our business

and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the civil False Claims Act, false statement laws and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious or fraudulent or knowingly making, using or causing to be made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal regulations relating to pricing and submission of pricing information for government programs, including penalties for knowingly and intentionally overcharging 340b eligible entities and the submission of false or fraudulent pricing information to government entities;
- HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by HITECH, and their respective implementing regulations, including the final omnibus rule published in January 2013, which impose obligations, including mandatory contractual terms, on certain covered healthcare providers, health plans and healthcare clearinghouses, as well as their respective business associates that perform services for them, that involve the use, or disclosure of, individually identifiable health information, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the Foreign Corrupt Practices Act, which prohibits companies and their intermediaries from making, or offering or promising to make improper payments to non-U.S. officials for the purpose of obtaining or retaining business or otherwise seeking favorable treatment;
- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the U.S. Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians, other healthcare providers and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payers, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring pharmaceutical manufacturers to report information related to payments to physicians and other healthcare providers, drug pricing or marketing expenditures. In addition, certain state and local laws require drug manufacturers to register pharmaceutical sales representatives. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, exclusion from government funded healthcare programs, such as Medicare and Medicaid, imprisonment, integrity oversight and reporting obligations and the curtailment or restructuring of our operations.

Healthcare reform

A primary trend in the United States healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States.

By way of example, the United States and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. In March 2010, the United States Congress enacted the ACA, which, among other things, includes changes to the coverage and payment for products under government healthcare programs.

Since enactment of the ACA, there have been, and continue to be, numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what effect further changes to the ACA would have on our business.

Further, there have been several U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products.

For example, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years. Drugs and biologics that have been approved for a single rare disease or condition were originally categorically excluded from price negotiation but, with passage of the One Big Beautiful Bill Act on July 3, 2025, Congress extended this exemption to drugs and biologics with multiple orphan drug designations.

Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated “maximum fair price” under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates if they raise prices for certain Part B and Part D drugs faster than the rate of inflation. The new law also caps Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at $2,000 a year.

The first cycle of negotiations for the Medicare Drug Price Negotiation Program commenced in the summer of 2023 with the negotiated prices for ten selected drug products becoming effective on January 1, 2026. The second cycle of negotiations with participating drug companies occurred during 2025, and

the negotiated prices for this second set of 15 drugs will become effective on January 1, 2027. On January 27, 2026, CMS published the list of 15 drugs selected for the third cycle of negotiations. These negotiated prices will become effective on January 1, 2028.

On June 6, 2023, Merck & Co. filed a lawsuit against HHS and CMS asserting that, among other things, the IRA's Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, a number of other parties also filed lawsuits in various courts with similar constitutional claims. HHS has generally won the substantive disputes in these cases or succeeded in getting claims dismissed for lack of standing or on the merits. For example, on May 8, 2025, the U.S. Court of Appeals for the Third Circuit rejected AstraZeneca L.P.'s challenge to the Medicare price negotiation program, finding that the program did not violate the company's due process rights under the Constitution. Litigation involving these and other provisions of the IRA will continue with unpredictable and uncertain results.

Since adoption of the IRA, the Trump Administration has taken a number of actions to reduce the costs of pharmaceutical products. For example, on April 15, 2025, President Trump issued an Executive Order which directs HHS to take steps to reduce the prices of pharmaceutical products. Further, on May 12, 2025, President Trump issued an additional Executive Order calling on pharmaceutical manufacturers to voluntarily reduce the prices of medicines in the United States. The Order provides that if such actions do not lower the costs of pharmaceuticals, the Secretary of HHS would pursue other actions, including proposing a rulemaking that imposes most favored nation, or MFN, pricing in the United States. Thereafter, on July 31, 2025, the President issued letters to 17 pharmaceutical companies reiterating the requirements of the May 12, 2025 Executive Order and demanding that such companies extend MFN pricing to Medicaid patients. Virtually all of these pharmaceutical companies have entered into agreements with the Administration to provide for lower prices on certain pharmaceuticals. On February 5, 2026, President Trump launched TrumpRx.gov, a website that directs individuals to pharmaceutical manufacturer websites that are offering price discounts based on the Administration's pricing agreements with pharmaceutical manufacturers.

Separately, on December 23, 2025, CMS, through its Center for Medicare and Medicaid Innovation, proposed two five-year pilot programs to implement a "reference pricing" regime for drugs paid for under Medicare for 25% of covered beneficiaries. The programs are referred to as the Global Benchmark for Efficient Drug Pricing Model for Medicare Part B drugs, referred to as GLOBE, and the Guarding U.S. Medicare Against Rising Drug Costs for Medicare Part D drugs, referred to as GUARD. Under the proposed pilot programs, a manufacturer would owe rebates to Medicare if prices for their drugs exceeded the prices paid by other economically comparable reference countries, defined in the proposed regulations as Organization for Economic Co-Operation and Development countries with a GDP of $400 billion and a per capita GDP that is at least 60% of the US per capita GDP (an initial list of 19 reference countries is included in the proposed rule). These pilot programs are proposed to go into effect beginning October 1, 2026.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. This is increasingly true with respect to products approved pursuant to the accelerated approval pathway. State Medicaid programs and other payers are developing strategies and implementing significant coverage barriers, or refusing to cover these products outright, arguing that accelerated approval drugs have insufficient or limited evidence despite meeting the FDA's standards for accelerated approval. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription product and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare

products and services, which could result in reduced demand for any product candidates we may develop or additional pricing pressures.

Employees and human capital

As of February 27, 2026, we had 258 full-time employees. Of the 258 employees, a total of 77 employees hold M.D. or Ph.D. degrees. Of these employees, 168 employees are engaged in research and development. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

We are committed to attracting, retaining, and developing our employees through comprehensive initiatives centered on enhancing engagement in our business and culture. We leverage a variety of networks, including our own employees, to recruit potential candidates and have a fair process to evaluate candidates for roles based on technical qualifications as well as fit within our organization. Also, as part of our efforts to develop the next generation of leaders in life sciences, we offer internships and co-op positions.

Developing and educating our employees are key to our organizational success. New employees benefit from a robust onboarding program that includes a comprehensive online platform. Employees utilize onboarding modules, including information on Dyne's platform, pipeline, benefits, and culture. Employees have scheduled one-on-one cross-functional meetings over the first few weeks of joining to ensure they feel welcomed and become familiar with colleagues and their areas of expertise. In addition, new employees work closely with their manager to plan and execute performance and development goals. Beyond onboarding, we offer development opportunities, prioritize regular feedback, and hold development discussions each quarter. We set aside time for these sessions for managers and employees to meet and discuss performance and career development.

In addition, we regularly evaluate the effectiveness of our talent management practices through employee surveys and fostering a culture of ongoing feedback. We track important talent metrics such as turnover rate and employee engagement. Voluntary and involuntary turnover rates across all levels are in alignment with, or lower than, the industry average.

To recruit and retain a talented, passionate and inclusive workforce with different experiences, perspectives and backgrounds, and to reward strong performance, we have competitive compensation and benefits programs for our employees and their families, including short-term and long-term incentives, exceptional health and wellness benefits along with vacation and leave programs.

Our equity and cash incentives are aimed to increase stockholder value and the success of our company by motivating our employees to perform to the best of their abilities and achieve our and their objectives. We also provide up to a 100% match on employee contributions (up to 4% with an annual maximum of $6,000) to our 401(k) retirement savings plan.

Our full-time U.S. employees are all eligible to participate in our health, vision, dental, and short-term and long-term disability insurance plans. To encourage employees to keep up with routine medical care and participate in our wellness program, we fund a health reimbursement account for participating employees and to help our employees cover medical and dependent care expenses pre-tax, we also offer employees a flexible spending account (FSA), and dependent care FSA.

We also have a cross-functional and multi-level team that is charged with identifying ways to reinforce our company values, bring insights from across the business, and drive initiatives, including team building, wellness, community, and patient events, such as toy donation drives, walks to support the neuromuscular disease community, and volunteer days.

Our corporate information

We were incorporated under the laws of the state of Delaware on December 1, 2017 under the name Dyne Therapeutics, Inc. Our principal executive offices are located at 1560 Trapelo Road, Waltham, Massachusetts 02451 and our telephone number is (781) 786-8230.

We own or have rights to trademarks, service marks and trade names that we use in connection with the operation of our business, including our corporate name, logos and website names. The service marks and trademarks that we own include the marks Dyne Therapeutics® and FORCE™. Other trademarks, service marks and trade names appearing in this Annual Report on Form 10-K are the property of their respective owners. Solely for convenience, some of the trademarks, service marks and trade names referred to in this Annual Report on Form 10-K are listed without the ® and ™ symbols, but we will assert, to the fullest extent under applicable law, our rights to our trademarks, service marks and trade names.

Available information

We file reports and other information with the Securities and Exchange Commission, or SEC, as required by the Securities Exchange Act of 1934, as amended, or the Exchange Act. You can review our electronically filed reports and other information that we file with the SEC on the SEC's website at http://www.sec.gov.

Our website address is https://www.dyne-tx.com. We make available free of charge through our website our Annual Report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Exchange Act. We make these reports available through our website as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the SEC. In addition, we regularly use our website to post information regarding our business, product development programs and governance, and we encourage investors to use our website, particularly the information in the section entitled "Investors & Media," as a source of information about us.

The foregoing references to our website are not intended to, nor shall they be deemed to, incorporate information on our website into this Annual Report on Form 10-K by reference. We have included our website address in this Annual Report on Form 10-K as an inactive textual reference.

Item 1A. Risk Factors.

Our business is subject to numerous risks. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this Annual Report on Form 10-K including our consolidated financial statements and the related notes thereto in evaluating our company. The risks described below are not the only risks facing our company. The occurrence of any of the following risks, or of additional risks and uncertainties not presently known to us or that we currently believe to be immaterial, could cause our business, prospects, operating results and financial condition to suffer materially.

Risks related to our financial position and need for additional capital

We have incurred significant losses since our inception, have no products approved for sale and we expect to incur losses for the foreseeable future.

Since inception, we have incurred significant operating losses. Our net losses were $446.2 million for the year ended December 31, 2025 and $317.4 million for the year ended December 31, 2024. As of December 31, 2025, we had an accumulated deficit of $1.4 billion. To date, we have financed our operations with the proceeds raised from the sale of equity securities and borrowing under the Loan Agreement with Hercules. We have devoted substantially all of our financial resources and efforts to research and development. Our product candidates are in varying stages of preclinical and clinical development and we have not completed clinical development of any product candidate. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our operating expenses and net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if and as we:

- advance our product candidates for DMD, DM1, FSHD and Pompe and any additional product candidates we may develop;
- expand the capabilities of our proprietary FORCE platform;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- obtain, expand, maintain, defend and enforce our intellectual property portfolio;
- hire additional clinical, regulatory and scientific personnel;
- establish manufacturing sources for any product candidate we may develop, including the Fab antibody, linker and therapeutic payload that will comprise the product candidate, and secure supply chain capacity to provide sufficient quantities for preclinical and clinical development and commercial supply;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval; and
- add operational, legal, compliance, financial and management information systems and personnel to support our research, product development and future commercialization efforts, as well as to support our operations as a public company.

Even if we obtain regulatory approval of, and are successful in commercializing, one or more of any product candidates we may develop, we will continue to incur substantial research and development and other costs to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

We have never generated revenue from product sales and may never achieve or maintain profitability.

Our product candidates are in varying stages of preclinical and clinical development. We have not completed clinical development of any product candidate, and we do not expect to have a product candidate ready for commercialization at least until 2027, if ever. To become and remain profitable, we

must succeed in developing, obtaining the necessary regulatory approvals for, and eventually commercializing a product or products that generate significant revenue. The ability to achieve this success will require us to be effective in a range of challenging activities, including:

- identifying product candidates and completing preclinical and clinical development of any product candidates we may identify and determine to develop;
- obtaining regulatory approval for any product candidates we may develop;
- manufacturing, marketing and selling any products for which we may obtain regulatory approval;
- achieving market acceptance of any products for which we obtain regulatory approval as a viable treatment option; and
- satisfying any post-marketing requirements.

We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. Our product candidates are in varying stages of preclinical and clinical development, and we have not completed clinical development of any product candidate. Because of the numerous risks and uncertainties associated with product development, we are unable to accurately estimate or know the nature, timing or costs of the efforts that will be necessary to complete the preclinical and clinical development and commercialization of any product candidate we may develop or when, or if, we will be able to generate revenues or achieve profitability.

If we are successful in obtaining regulatory approval to market one or more of our products, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could impair our ability to raise capital, maintain our research and development efforts, expand our business or even continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

We will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development activities or commercialization efforts.

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the clinical development of z-rostudirsen and z-basivarsen, and the preclinical and clinical development of DYNE-302, our FSHD product candidate, DYNE-401, our Pompe disease product candidate, and DYNE-253, DYNE-245, DYNE-244 and DYNE-255, our product candidates for DMD amenable to skipping exons 53, 45, 44 and 55, respectively, and any additional product candidates we may develop, and arrange for the manufacturing of, and potentially seek marketing approval for any product candidates we may develop. In addition, if we obtain marketing approval for any product candidates we may develop, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed, on attractive terms or at all, we may be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

As of December 31, 2025, we had cash, cash equivalents and marketable securities of $1.1 billion.

We believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses, debt service obligations and capital expenditure requirements into the first quarter of 2028. However, we have based these estimates on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. As a result, we could deplete our capital resources sooner than we currently expect and could be forced to seek additional funding sooner than planned.

Our future capital requirements will depend on many factors, including:

- the identification of additional product candidates;
- the scope, progress, costs and results of preclinical and clinical development of any product candidates we may develop;
- the costs, timing and outcome of regulatory review of any product candidates we may develop;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- changes in laws or regulations applicable to any product candidates we may develop, including but not limited to clinical trial requirements for approvals;
- the cost and timing of obtaining materials to produce adequate product supply for any preclinical or clinical development of any product candidate we may develop;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any product candidate we may develop for which we obtain marketing approval;
- the legal costs involved in prosecuting patent applications and enforcing patent claims and other intellectual property claims;
- additions or departures of key scientific or management personnel;
- our ability to establish and maintain collaborations on favorable terms, if at all, as well as the costs and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder; and
- the costs of operating as a public company.

Identifying product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, even if we successfully identify and develop product candidates and those are approved, we may not achieve commercial success. Our commercial revenues, if any, may not be sufficient to sustain our operations. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our operations. We cannot be certain that additional funding will be available on acceptable terms, when needed or at all. Other than the Loan Agreement with Hercules, we have no committed source of additional capital and, if we are unable to raise additional capital in sufficient amounts, when needed or on terms acceptable to us, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidates we may develop, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations. We could be required to seek collaborators for product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and/or licensing arrangements, and terms loans under our Loan Agreement with Hercules. For example, in June 2025, we entered into the Loan Agreement with Hercules providing for term loans in an aggregate principal amount of up to $275.0 million under multiple tranches, available as follows: (i) an initial term loan tranche funded on the closing date of the Loan Agreement in aggregate principal amount of $100.0 million; (ii) subject to the achievement of specified clinical, regulatory and commercial milestones, three additional term loan tranches totaling up to $115.0 million; and (iii) subject to approval by the Lenders' investment committee in their discretion, a final term loan tranche of up to $60.0 million. In December 2025, we entered into the First Amendment to the Loan Agreement, or the First Amendment, pursuant to which a second term loan tranche was funded in an aggregate principal amount of $50.0 million. Following entry into the First Amendment and the borrowing of the second term loan tranche, we have two additional term loan tranches we may borrow pursuant to the Loan Agreement, totaling up to $75.0 million, which are available subject to the achievement of specified clinical, regulatory and commercial milestones, and a final term loan tranche of up to $50.0 million, which is available subject to approval by the Hercules investment committee in its discretion. However, if we do not satisfy the specified clinical, regulatory and commercial milestones or the Lenders do not otherwise approve the discretionary tranche, we may not have access to the remaining amounts under the term loans. Other than the Loan Agreement with Hercules, we do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Any debt financing or preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, selling or licensing our assets, making capital expenditures, declaring dividends or encumbering our assets to secure future indebtedness.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed or on terms acceptable to us, we may be required to delay, limit, reduce or eliminate some or all of our research and development programs, pipeline expansion or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.

We commenced operations in 2017, and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, conducting research and development activities and filing and prosecuting patent applications. Our product candidates are in varying stages of preclinical and clinical development, and their risk of failure is high. We have not yet demonstrated our ability to complete the clinical development of any product candidate, obtain marketing approvals, manufacture product on a commercial scale or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing products.

Our limited operating history may make it difficult to evaluate our technology and industry and predict our future performance. Our limited history as an operating company makes any assessment of our future success or viability subject to significant uncertainty. We will encounter risks and difficulties frequently

experienced by clinical-stage companies in rapidly evolving fields. If we do not address these risks successfully, our business will suffer.

In addition, as our business grows, we may encounter unforeseen expenses, restrictions, difficulties, complications, delays and other known and unknown factors. We are in the process of transitioning from a company focused on conducting development activities to a company capable of supporting commercial activities. We may not be successful in such a transition.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be subject to limitations.

We have a history of cumulative losses and anticipate that we will continue to incur significant losses in the foreseeable future; thus, we do not know whether or when we will generate taxable income necessary to utilize our net operating losses, or NOLs, or research and development tax credit carryforwards. As of December 31, 2025, we had federal NOL carryforwards of $981.6 million and state NOL carryforwards of $1.0 billion.

In general, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, a corporation that undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, is subject to limitations on its ability to utilize its pre-change NOLs and pre-change research and development tax credit carryforwards to offset post-change taxable income. We completed a Section 382 study of transactions in our stock through December 10, 2025 and concluded that we have experienced ownership changes since inception that we believe under Sections 382 and 383 of the Code will result in limitations in our ability to use certain pre-change NOLs and credits. We will continue to analyze the impacts of Section 382 from future transactions in our stock. In the future, we may experience additional ownership changes as a result of equity offerings or other changes in the ownership of our stock, some of which are beyond our control. As a result, if, and to the extent that, we earn net taxable income, our ability to use our NOL carryforwards and research and development tax credit carryforwards to offset such taxable income may be subject to limitations.

There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise become unavailable to offset future income tax liabilities. In addition, state NOLs generated in one state cannot be used to offset income generated in another state. For these reasons, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes.

Risks related to our indebtedness

Our Loan Agreement contains restrictive and financial covenants that may limit our operating flexibility.

On June 27, 2025, we entered into the Loan Agreement with Hercules and the other lenders party thereto, which we refer to as the Lenders, providing for term loans in an aggregate principal amount of up to $275.0 million available as follows: (i) an initial term loan tranche funded on June 27, 2025 in an aggregate principal amount of $100.0 million; (ii) subject to the achievement of specified clinical, regulatory and commercial milestones, three additional term loan tranches totaling up to $115.0 million; and (iii) subject to approval by the Lenders' investment committee in their discretion, a final term loan tranche of up to $60.0 million. In December 2025, we entered into the First Amendment, pursuant to which a second term loan tranche was funded in an aggregate principal amount of $50.0 million. Following entry into the First Amendment and the borrowing of the second term loan tranche, we have two additional term loan tranches we may borrow pursuant to the Loan Agreement, totaling up to $75.0 million, which are available subject to the achievement of specified clinical, regulatory and commercial milestones, and a final term loan tranche of up to $50.0 million, which is available subject to approval by the Lenders' investment committee in their discretion. Our obligations under the Loan Agreement are secured by a first-priority security interest in substantially all of our property, inclusive of intellectual property, subject to customary permitted liens and other exceptions set forth in the Loan Agreement.

The Loan Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including a minimum cash covenant, which we refer to as the Minimum Cash Covenant, requiring that we maintain specified levels of cash in accounts subject to a control agreement in favor of Hercules, or the Qualified Cash, during the period commencing on January 1, 2027. The Minimum Cash Covenant will initially be set at 60% of the then outstanding obligations under the Loan Agreement, is subject to adjustment and will not be tested at any time when our market capitalization is greater than $1.65 billion. We are also required to maintain minimum net product revenue from the sale of z-rostudirsen and z-basivarsen starting nine months after FDA approval of z-rostudirsen or z-basivarsen, which we refer to as the Minimum Revenue Covenant, if the outstanding obligations under the Loan Agreement exceed $100.0 million. The Minimum Revenue Covenant will not be tested for any month to the extent that for each day during such month either (i) Qualified Cash is at least 100% of our outstanding obligations under the Loan Agreement or (ii) our market capitalization is greater than $1.65 billion and Qualified Cash is at least 50% of our outstanding obligations under the Loan Agreement. Certain negative covenants under the Loan Agreement limit our ability, among other things, to incur future debt, grant liens, make investments, make acquisitions, distribute dividends, enter into transactions with affiliates, make payments on other indebtedness and sell assets, subject in each case to certain exceptions. Our business may be adversely affected by these restrictions on our ability to operate our business. If we raise any additional debt financing, as permitted by the Loan Agreement, the terms of such additional indebtedness could further restrict our operating and financial flexibility.

We may not be able to generate sufficient cash flow or sales to meet the Minimum Cash Covenant or the Minimum Revenue Covenant or pay the outstanding obligations under the Loan Agreement when due. Furthermore, our future working capital, borrowings or equity financings could be unavailable to repay or refinance the amounts outstanding under the Loan Agreement. In the event of a liquidation of our business, we would be required to repay all outstanding obligations under the Loan Agreement prior to the distribution of assets to unsecured creditors, and the holders of our common stock would receive a portion of any liquidation proceeds only if all of our creditors then existing, including the lenders under our Loan Agreement with Hercules, were first repaid in full.

If we fail to comply with the Minimum Cash Covenant, the Minimum Revenue Covenant or the other covenants under the Loan Agreement, it will result in an event of default. Upon the occurrence of an event of default, and subject to any specified cure periods, all amounts owed under the Loan Agreement may be declared immediately due and payable by the Lenders, and the Lenders may foreclose on collateral.

Our failure to comply with the covenants or other terms of the Loan Agreement, including as a result of events beyond our control, could result in a default under the Loan Agreement that could materially and adversely affect our business.

We may be required to repay the outstanding indebtedness under the Loan Agreement if an event of default occurs under the Loan Agreement or, if applicable, any future debt facility. The Loan Agreement includes customary events of default, including payment defaults, breaches of covenants following any applicable cure period, the occurrence of certain events that could reasonably be expected to have a "material adverse effect" as set forth in the Loan Agreement and cross acceleration. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time any such event of default occurs. In this case, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events.

Risks related to discovery and development

Our product candidates are in varying stages of preclinical and clinical development and we have not completed clinical development of any product candidate. We do not expect to complete the

commercialization of any product candidate at least until 2027, if ever. If we are unable to identify and advance product candidates through preclinical studies and clinical trials, obtain marketing approval and ultimately commercialize them, or experience significant delays in doing so, our business will be materially harmed.

We have focused our efforts to date on developing our platform, identifying our programs and conducting the clinical development of our product candidates. Our product candidates are in varying stages of preclinical and clinical development, and we have not completed clinical development of any product candidate. Our ability to generate product revenue, which we do not expect will occur until at least 2027, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates, which may never occur. We currently generate no revenue from sales of any product, and we may never be able to develop or commercialize a marketable product.

Commencing clinical trials in the United States is subject to acceptance by the FDA, of an IND and finalizing the trial design based on discussions with the FDA and other regulatory authorities. In the event that the FDA requires us to complete additional preclinical studies or we are required to satisfy other FDA requests prior to commencing clinical trials, the start of any future clinical trials may be delayed. Even after we receive and incorporate guidance from the FDA, the FDA could disagree that we have satisfied their requirements to commence any clinical trial or change their position on the acceptability of our trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials or impose stricter approval conditions than we currently expect.

For example, the FDA placed on clinical hold our IND application to initiate a clinical trial of z-rostudirsen in patients with DMD amenable to skipping exon 51. We received a clinical hold letter from the FDA in January 2022 requesting additional clinical and non-clinical information for z-rostudirsen, which we submitted before the FDA ultimately cleared the IND in July 2022.

There are equivalent processes and risks applicable to clinical trial applications in other countries, including countries in the European Union.

Commercialization of any product candidates we may develop will require preclinical and clinical development; regulatory and marketing approval in any jurisdiction where we seek to commercialize such product candidates, such as the FDA and the European Medicines Agency, or EMA; manufacturing supply, capacity and expertise; a commercial organization; and significant marketing efforts. The success of product candidates we may develop will depend on many factors, including the following:

- timely and successful completion of preclinical studies;
- effective INDs or comparable foreign applications that allow commencement of clinical trials or future clinical trials for any product candidates we may develop;
- successful enrollment and completion of clinical trials, including under the FDA's current Good Clinical Practices, or cGCPs, current Good Laboratory Practices, or cGLPs, and any additional regulatory requirements from foreign regulatory authorities;
- positive results from our clinical trials or future clinical trials that support a finding of safety and effectiveness and an acceptable risk-benefit profile in the intended populations;
- receipt of marketing approvals from applicable regulatory authorities;
- establishment of arrangements through our own facilities or with third-party manufacturers for clinical supply and, where applicable, commercial manufacturing capabilities;
- establishment, maintenance, defense and enforcement of patent, trademark, trade secret and other intellectual property protection or regulatory exclusivity for any product candidates we may develop;
- commercial launch of any product candidates we may develop, if approved, whether alone or in collaboration with others;

- acceptance of the benefits and use of our product candidates we may develop, including method of administration, if and when approved, by patients, the medical community and third-party payers;
- effective competition with other therapies;
- maintenance of a continued acceptable safety, tolerability and efficacy profile of any product candidates we may develop following approval; and
- establishment and maintenance of healthcare coverage and adequate reimbursement by payers.

If we do not succeed in one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize any product candidates we may develop, which would materially harm our business. If we are unable to advance our product candidates into and through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We may encounter substantial delays in commencement, enrollment or completion of our clinical trials and the data from the clinical trials of our product candidates may fail to demonstrate sufficient safety and efficacy to the satisfaction of applicable regulatory authorities, which could prevent us from commercializing any product candidates on a timely basis, if at all.

The risk of failure in developing product candidates is high. It is impossible to predict when or if any product candidate would prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of product candidates in humans. We have not yet completed clinical development of any product candidate. Clinical trials may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. Even if the clinical trials are successful, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application.

Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our INDs and other regulatory filings. We cannot be certain of the timely identification of a product candidate or the completion or outcome of our preclinical testing and studies and cannot predict whether the FDA will accept our proposed clinical programs or whether the outcome of our preclinical testing and studies will ultimately support the further development of any product candidates. Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. As a result, we cannot be sure that we will be able to submit INDs for our preclinical product candidates on the timelines we expect, if at all, and we cannot be sure that submission of INDs will result in the FDA allowing clinical trials to begin in the United States.

Furthermore, product candidates are subject to continued preclinical safety studies, which may be conducted concurrently with our clinical testing. The outcomes of these safety studies may delay the launch of or enrollment in clinical trials and could impact our ability to continue to conduct our clinical trials.

Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, or at all. A failure of one or more clinical trials can occur at any stage of testing, which may result from a multitude of factors, including, but not limited to, flaws in trial design, dose selection issues, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits.

Other events that may prevent successful or timely completion of clinical development include:

- delays in reaching a consensus with regulatory authorities on trial design;

- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- delays in opening clinical trial sites or obtaining required institutional review board, or IRB, or independent ethics committee approval, or the equivalent review groups for sites outside the United States, at each clinical trial site;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event or after an inspection of our clinical trial operations or trial sites;
- negative or inconclusive results observed in clinical trials, including failure to demonstrate statistical significance, which could lead us, or cause regulators to require us, to conduct additional clinical trials or abandon product development programs;
- failure by us, any CROs we engage or any other third parties to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA's cGCPs;
- failure by physicians to adhere to delivery protocols leading to variable results;
- delays in the testing, validation, manufacturing and delivery of any product candidates we may develop to the clinical sites, including delays by third parties with whom we have contracted to perform certain of those functions;
- failure of our third-party contractors to comply with regulatory requirements or to meet their contractual obligations to us in a timely manner, or at all;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical trial sites or patients dropping out of a trial;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- occurrence of serious adverse events associated with a product candidate in development by another company, which are viewed to outweigh its potential benefits, and which may negatively impact the perception of our product due to a similarity in technology or approach;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the legal or regulatory regimes domestically or internationally related to patient rights and privacy; or
- lack of adequate funding to continue the clinical trial.

Any inability to successfully complete preclinical studies and clinical trials could result in additional costs to us or impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. In addition, if we make manufacturing or formulation changes to any product candidates, we may need to conduct additional studies or trials to bridge our modified product candidates to earlier versions. Clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize any product candidates we may develop or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize any product candidates we may develop and may harm our business, financial condition, results of operations and prospects.

Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with any product candidates we may develop, we may:

- be delayed in obtaining marketing approval for product candidates, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;

- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to changes in the way the product is administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

In particular, each of the conditions for which we plan to develop product candidates are rare genetic diseases with limited patient pools from which to draw for clinical trials. Further, because it can be difficult to diagnose these diseases in the absence of a genetic screen, we may have difficulty finding patients who are eligible to participate in our studies. The eligibility criteria of our clinical trials will further limit the pool of available study participants. Additionally, the process of finding and diagnosing patients may prove costly. The treating physicians in our clinical trials may also use their medical discretion in advising patients enrolled in our clinical trials to withdraw from our studies to try alternative therapies.

In addition, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted. For example, in December 2022, with the passage of FDORA, Congress required sponsors to develop and submit a Diversity Action Plan, or DAP, for each phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for the DAPs. Unlike most guidance documents issued by the FDA, the DAP guidance, when finalized, will have the force of law as FDORA specifically dictates that the form and manner for submission of DAPs are specified in FDA guidance.

On January 27, 2025, in response to an executive order issued by President Trump on January 21, 2025 on diversity, equity and inclusion programs, the FDA removed the draft DAP guidance from its website. Subsequently, in July 2025, pursuant to a court order, the FDA restored the draft DAP guidance to its website with a statement that "information on this page may be modified and/or removed in the future subject to the terms of the court's order and implemented consistent with applicable law." Accordingly, in light of these ongoing actions, there is considerable uncertainty surrounding the draft DAP guidance and how the FDA will consider diversity action plans in connection with its review of applications for marketing approval.

The regulatory landscape related to clinical trials in the European Union has also evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state, to both the competent national health authority and an independent ethics committee, the CTR introduced a centralized process and only requires the submission of a single application to all member states concerned. If we are not able to fulfill these requirements, our ability to conduct clinical trials may be delayed or halted.

Our approach to the discovery and development of product candidates based on our FORCE platform is unproven, and we may not be successful in our efforts to identify, discover or develop potential product candidates.

The success of our business depends upon our ability to identify, develop and commercialize products based on our proprietary FORCE platform. Our therapeutics are constructed from three components: a proprietary Fab, a linker and a therapeutic payload that we attach to our Fab using the linker. The Fab is

engineered to bind to TfR1 to enable targeted delivery of nucleic acids and other molecules to skeletal, cardiac and smooth muscle.

All of our product candidates are still in varying stages of preclinical and clinical development, and our approach to treating muscle disease is unproven. Our research programs may fail to identify additional product candidates for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying additional potential product candidates and our potential product candidates may be shown to have harmful side effects in preclinical *in vitro* experiments or animal model studies. In addition, our product candidates may not show promising signals of therapeutic effect in such experiments or studies or they may have other characteristics that may make the product candidates impractical to manufacture, unmarketable or unlikely to receive marketing approval. Further, because all of our product candidates and programs are based on our FORCE platform, adverse developments with respect to one of our product candidates and programs may have a significant adverse impact on the actual or perceived likelihood of success and value of our other product candidates and programs.

In addition, we have not completed clinical development of any product candidate or successfully developed any product candidates, and our ability to identify and develop product candidates may never materialize. The process by which we identify and develop product candidates may fail to yield product candidates for clinical development for a number of reasons, including those discussed in these risk factors. In addition:

- we may not be able to assemble sufficient resources to acquire or discover product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties' patents or other intellectual property rights;
- product candidates may, on further study, be shown to have harmful side effects, toxicities or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance;
- product candidates may not be effective in treating their targeted diseases or disorders;
- the market for a product candidate may change so that the continued development of that product candidate is no longer reasonable;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or
- the regulatory pathway for a product candidate may be too complex and difficult to navigate successfully or economically.

If we are unable to identify and discover suitable product candidates for clinical development, this would adversely impact our business strategy and our financial position and share price and could potentially cause us to cease operations.

The outcome of preclinical studies and data from earlier-stage clinical trials may not be predictive of final results or future results of clinical trials or the success of later clinical trials and data from clinical trials in one indication may not be predictive of results of clinical trials in other indications.

We have not completed clinical development of any product candidate. As a result, our belief in the capabilities of our platform, including our belief that we have demonstrated proof of concept of our FORCE platform, is based on early research, preclinical studies and data from clinical trials of our product candidates. However, the results of preclinical studies may not be predictive of the results of later preclinical studies or clinical trials, and the initial results of any clinical trials, such as initial results of DELIVER and ACHIEVE that we have reported, may not be predictive of the final results of those trials or the results of any later clinical trials, and may also not be predictive of results of clinical trials in other indications. Moreover, preclinical and clinical data are often susceptible to varying interpretations and

analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Further, certain of our hypotheses regarding the potential benefits of our product candidates compared to alternative therapies and treatments are based on cross-trial comparisons of results that were not derived from head-to-head clinical trials. Such clinical trial data may not be directly comparable due to differences in study protocols, conditions and patient populations. Accordingly, these cross-trial comparisons may not be reliable predictors of the relative efficacy or other benefits of our product candidates compared to other product candidates that may have been approved previously.

Our clinical trials may not ultimately be successful or support further clinical development of any product candidates we may develop. There is a high failure rate for product candidates proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving encouraging results in earlier studies. Any such setbacks in our clinical development could materially harm our business and results of operations.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our ability to complete clinical trials may be adversely impacted.

Identifying and qualifying patients to participate in clinical trials of any product candidates we may develop is critical to our success. We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics, to complete our clinical trials in a timely manner. Patient enrollment and trial completion is affected by factors including:

- perceived risks and benefits of novel unproven approaches;
- size of the patient population, in particular for rare diseases such as the diseases on which we are initially focused, and process for identifying patients;
- design of the trial protocol;
- eligibility and exclusion criteria;
- perceived risks and benefits of the product candidate under study;
- availability of competing therapies and clinical trials;
- severity of the disease or disorder under investigation;
- proximity and availability of clinical trial sites for prospective patients;
- ability to obtain and maintain patient consent;
- risk that enrolled patients will drop out before completion of the trial;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in these clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Furthermore, we rely on and expect to continue to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we will have limited influence over their performance.

Even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining patients in our clinical trials. Many of the patients who end up receiving placebo may perceive that they are not receiving the product candidate being tested, and they may decide to withdraw from our clinical trials to pursue other alternative therapies rather than continue the trial with the perception that they are receiving placebo. If we have difficulty enrolling or maintaining a sufficient number of patients to conduct our clinical trials, we may need to delay, limit or terminate clinical trials, any of which would harm our business, financial condition, results of operations and prospects.

If any product candidates we may develop cause undesirable side effects or have other unexpected adverse properties, such side effects or properties could delay or prevent us from conducting clinical trials or seeking or obtaining regulatory approval, limit the commercial potential of our product candidates or result in significant negative consequences to the extent such effects or adverse properties are observed following any marketing approval.

We have not completed clinical development of any product candidate. It is impossible to predict when or if any product candidates we may develop will prove safe in humans. There can be no assurance that our technologies will not cause undesirable side effects.

Although other oligonucleotide therapeutics have received regulatory approval, our approach for our DMD and DM1 programs, which combine oligonucleotides with a Fab, is a novel approach to oligonucleotide therapy. As a result, there is uncertainty as to the safety profile of product candidates we may develop compared to more well-established classes of therapies, or oligonucleotide therapeutics on their own. Moreover, there have been only a limited number of clinical trials involving the use of conjugated oligonucleotide therapeutics.

If any product candidates we develop are associated with serious adverse events, undesirable side effects or unexpected characteristics, we may need to abandon their development or limit development to certain uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, any of which would have a material adverse effect on our business, financial condition, results of operations and prospects. Many product candidates that initially showed promise in early-stage testing have later been found to cause side effects that prevented further clinical development of the product candidates.

If in the future we are unable to demonstrate that such side effects were caused by factors other than our product candidates, the FDA, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, any product candidates for any or all targeted indications. Even if we are able to demonstrate that any future serious adverse events are not product-related and regulatory authorities do not order us to cease further development of our product candidates, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of any product candidate, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may harm our business, financial condition and prospects significantly.

We may expend our limited resources to pursue a particular program, product candidate or indication and fail to capitalize on programs, product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications among many potential options. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential, or we may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable medicines. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Any such event could have a material adverse effect on our business, financial condition, results of operations and prospects.

Clinical trial and product liability lawsuits against us could divert our resources, could cause us to incur substantial liabilities and could limit commercialization of our product candidates.

We will face an inherent risk of clinical trial and product liability exposure related to the testing of our product candidates in clinical trials, and we will face an even greater risk if we commercially sell any products that we may develop. While we currently have no product candidates that have been approved for commercial sale, the use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies or others selling such products. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend any related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any product candidates we may develop.

We have increased our insurance coverage in countries in which we plan to conduct clinical trials and will need to increase our insurance coverage if we conduct clinical trials in additional countries or of additional product candidates or if we commence commercialization of any product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful clinical trial or product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Risks related to our dependence on third parties

We rely, and expect to continue to rely, on third parties to conduct some or all aspects of our product manufacturing, or our research and preclinical and clinical testing, and these third parties may not perform satisfactorily.

We do not expect to independently conduct all aspects of our product manufacturing, or our research and preclinical and clinical testing. We currently rely, and expect to continue to rely, on third parties with respect to many of these items, including CMOs, for the manufacturing of any product candidates we test in preclinical or clinical development, as well as CROs for portions of our animal testing, preclinical research and for the conduct of our clinical trials. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it could delay our product development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations and study protocols. For example, for product candidates that we develop and commercialize on our own, we will remain responsible for ensuring that each of our IND/CTA-enabling studies and clinical trials are conducted in accordance with the study plan and protocols. Moreover, the FDA requires us to comply with cGCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. If we or

any of our CROs or other third parties, including trial sites, fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with cGCP regulations. In addition, our clinical trials must be conducted with product produced under conditions that comply with the FDA's current Good Manufacturing Practices. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Although we design the clinical trials for our product candidates, CROs conduct some or all of the clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct preclinical studies and clinical trials will also result in less direct control over the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our preclinical studies and clinical trials and may subject us to unexpected cost increases that are beyond our control. In addition, any third parties conducting our clinical trials will not be our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our clinical programs. If the CROs and other third parties do not perform preclinical studies and clinical trials in a satisfactory manner, if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, or if they breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of any product candidates we may develop may be delayed, we may not be able to obtain regulatory approval and commercialize our product candidates or our development programs may be materially and irreversibly harmed. If we are unable to rely on preclinical and clinical data collected by our CROs and other third parties, we could be required to repeat, extend the duration of or increase the size of any preclinical studies or clinical trials we conduct and this could significantly delay commercialization and require greater expenditures.

If third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, we will not be able to complete, or may be delayed in completing, the preclinical studies and clinical trials required to support future IND submissions and approval of any product candidates we may develop.

We currently depend on a small number of third-party suppliers for the manufacture of our Fab, the linkers and payloads. The loss of these or future third-party suppliers, or their inability to provide us with sufficient supply, could harm our business.

We do not own or operate manufacturing facilities and have no current plans to develop our own clinical or commercial-scale manufacturing capabilities. In the future, we may seek to establish our own manufacturing facility for the long-term commercial supply of any product candidates we may develop and which receive regulatory approval. We rely on a small number of third-party suppliers for the manufacture of our Fab, linkers and payloads. We expect to continue to depend on third-party suppliers for the manufacture of any product candidates that we evaluate in preclinical studies and clinical trials, as well as for commercial manufacture if those product candidates receive marketing approval. The facilities used by third-party manufacturers to manufacture our product candidates must be approved by the FDA and any

comparable foreign regulatory authority pursuant to inspections that will be conducted after we submit a biologics license application, or BLA, to the FDA or any comparable filing to a foreign regulatory authority. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP requirements for manufacture of products. If these third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or any comparable foreign regulatory authority, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities.

Our product candidates consist of a proprietary Fab conjugated with a linker to a payload. Our Fab is manufactured by starting with cells which are stored in a cell bank. If we lose multiple cell banks, our manufacturing will be adversely impacted by the need to replace the cell banks.

In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any comparable foreign regulatory authority does not approve these facilities for the manufacture of any product candidates we may develop or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market any product candidates we may develop, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates. In addition, certain Chinese biotechnology companies and CMOs that supply us with drug components may become subject to trade restrictions, sanctions, and other regulatory requirements by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting the supply of material to us. Such disruption could have adverse effects on the development of our product candidates and our business operations.

We may also seek to eventually establish our own manufacturing facility for the long-term commercial supply of any product candidates we may develop and which receive regulatory approval. If we determine to establish our own manufacturing facility and manufacture our products on our own, we will need to obtain the resources and expertise in order to build such manufacturing capabilities and to conduct such manufacturing operations. In addition, our conduct of such manufacturing operations will be subject to the extensive regulations and operational risks to which our third-party suppliers are subject. If we are not successful in building these capabilities or complying with the regulations or otherwise operating our manufacturing function, our commercial supply could be disrupted and our business could be materially harmed.

Our or a third party's failure to execute on our manufacturing requirements on commercially reasonable terms and in compliance with cGMP could adversely affect our business in a number of ways, including:

- an inability to initiate preclinical studies or clinical trials of product candidates;
- delays in submitting regulatory applications, or receiving marketing approvals, for product candidates;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of product candidates; and
- in the event of approval to market and commercialize any product, an inability to meet commercial demands for the product.

We are party to manufacturing agreements with a number of third-party manufacturers. We may be unable to maintain these agreements or establish any additional agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to maintain or establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third party;
- failure to manufacture according to our specifications;
- failure to manufacture according to our schedule or at all;
- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

We may compete with third parties for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

We do not currently have arrangements in place for redundant supply or a second source for all required raw materials. If our existing or future third-party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all.

Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in supply. An alternative manufacturer would need to be qualified through a BLA supplement which could result in further delay. The regulatory agencies may also require additional studies or trials if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully. Furthermore, if our suppliers fail to meet contractual requirements, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

Our current and anticipated future dependence upon third parties for the manufacture of any product candidates we develop may adversely affect our development programs and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We may from time to time be dependent on single-source suppliers for some of the components and materials used in the product candidates we may develop.

We may from time to time depend on single-source suppliers for some of the components and materials used in any product candidate we may develop. For instance, we currently use a single or limited number of suppliers for each of our Fab, linkers and payloads. We cannot ensure that these suppliers or service providers will remain in business, have sufficient capacity or supply to meet our needs or that they will not be purchased by one of our competitors or another company that is not interested in continuing to work with us. Our use of single-source suppliers of raw materials, components, key processes and finished goods could expose us to several risks, including disruptions in supply, price increases or late deliveries. There are, in general, relatively few alternative sources of supply for substitute components. These vendors may be unable or unwilling to meet our future demands for our clinical trials or commercial sale. Establishing additional or replacement suppliers for these components, materials and processes could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. Any disruption in supply from any single-source supplier or service provider could lead to supply delays or interruptions which would damage our business, financial condition, results of operations and prospects.

If we have to switch to a replacement supplier, the manufacture and delivery of any product candidates we may develop could be interrupted for an extended period, which could adversely affect our business. Establishing additional or replacement suppliers, if required, may not be accomplished quickly. If we are

able to find a replacement supplier, the replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. While we seek to maintain adequate inventory of the single source components and materials used in our products, any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand for our investigational medicines.

We may enter into collaborations with third parties for the research, development and commercialization of certain of the product candidates we may develop. If any such collaborations are not successful, we may not be able to capitalize on the market potential of those product candidates.

We may seek third-party collaborators for the research, development and commercialization of certain of the product candidates we may develop. If we enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into.

Collaborations involving our research programs or any product candidates we may develop pose numerous risks to us, including the following:

- collaborators would have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development and commercialization of any product candidates we may develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay programs, preclinical studies or clinical trials, provide insufficient funding for programs, preclinical studies or clinical trials, stop a preclinical study or clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with any product candidates we may develop if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators may be acquired by a third party having competitive products or different priorities, causing the emphasis on our product development or commercialization program under such collaboration to be delayed, diminished or terminated;
- collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- collaborators may not properly obtain, maintain, enforce or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development, or commercialization of any product candidates we may develop or that result in costly litigation or arbitration that diverts management attention and resources;
- we may lose certain valuable rights under certain circumstances, including if we undergo a change of control;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates we may develop; and

- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all.

If our collaborations do not result in the successful development and commercialization of product candidates, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of product candidates could be delayed, and we may need additional resources to develop product candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval and commercialization described in this “Risk Factors” section apply to the activities of our collaborators.

These relationships, or those like them, may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. If we license rights to any product candidates we or our collaborators may develop, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture.

If conflicts arise between us and our potential collaborators, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.

If conflicts arise between us and our potential collaborators, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Our collaborators may develop, either alone or with others, products in related fields that are competitive with the product candidates we may develop that are the subject of these collaborations with us. Competing products, either developed by the collaborators or to which the collaborators have rights, may result in the withdrawal of support for our product candidates.

Some of our future collaborators could also become our competitors. Our collaborators could develop competing products, preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely, fail to devote sufficient resources to the development and commercialization of products, or merge with or be acquired by a third party who may do any of these things. Any of these developments could harm our product development efforts.

If we are not able to establish collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our research programs and product candidates and the potential commercialization of any product candidates we may develop will require substantial additional cash to fund expenses. For some of the product candidates we may develop, we may decide to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator’s resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator’s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, the EMA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative

product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization, reduce the scope of any sales or marketing activities, or increase our own expenditures on the development of the product candidate.

We are dependent on third-party vendors to provide certain licenses, products and services and our business and operations, including clinical trials, could be disrupted by any problems with our significant third-party vendors.

We engage a number of third-party suppliers and service providers to supply critical goods and services, such as contract research services, contract manufacturing services and IT services. Disruptions to the business, financial stability or operations of these suppliers and service providers, including due to strikes, labor disputes or other disruptions to the workforce or to their willingness and ability to produce or deliver such products or provide such services in a manner that satisfies the requirements put forth by the authorities, or in a manner that satisfies our own requirements, could affect our ability to develop and market our future product candidates on a timely basis. If these suppliers and service providers were unable or unwilling to continue to provide their products or services in the manner expected, or at all, we could encounter difficulty finding alternative suppliers. Even if we are able to secure appropriate alternative suppliers in a timely manner, costs for such products or services could increase significantly. Any of these events could adversely affect our results of operations and our business.

Risks related to commercialization

We face substantial competition, which may result in others discovering, developing or commercializing products before us or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to any product candidates that we may develop from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of many of the disorders for which we are conducting research and development programs. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than our product candidates or that would render any product candidates that we may develop obsolete or non-competitive. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates we may develop against competitors.

Currently, patients with DMD are treated with corticosteroids to manage the inflammatory component of the disease. EMFLAZA (deflazacort) is an FDA-approved corticosteroid marketed by PTC Therapeutics,

Inc.. A novel steroid, AGAMREE (vamorolone) has also been approved by the FDA for treatment of DMD in patients 2 years of age and older and is marketed by Catalyst Pharmaceuticals, Inc. Givinostat, an HDAC inhibitor, received FDA approval for treatment of DMD in patients 6 years of age and older and is marketed in the United States by ITF Therapeutics, LLC. In addition, there are four FDA-approved exon skipping drugs: EXONDYS 51 (eteplirsen), VYONDYS 53 (golodirsen) and AMONDYS 45 (casimersen), which are naked PMOs approved for the treatment of DMD patients amenable to exon 51, exon 53 and exon 45 skipping, respectively, and are marketed by Sarepta, and VILTEPSO (vitolarsen), a naked PMO approved for the treatment of DMD patients amenable to exon 53 skipping, which is marketed by Nippon Shinyaku Co. Ltd. Additionally, there is one FDA-approved gene therapy for patients with a confirmed mutation in the dystrophin gene, ELEVIDYS (delandistrogene moxeparvovec-rokl), which is marketed by Sarepta. Companies focused on developing treatments for DMD that target dystrophin mechanisms, as does our DMD program, include Wave Life Sciences Ltd. with WVE-N531, a stereopure oligonucleotide being evaluated in a Phase 2 clinical trial for patients amenable to exon 53 skipping; Entrada Therapeutics, Inc. with ENTR-601-44, an endosomal escape vehicle technology for the treatment of DMD patients amenable to exon 44 and exon 45 skipping, respectively, currently being evaluated in Phase 1/2 clinical trials; BioMarin Pharmaceuticals, Inc. with BMN-351, an ASO for patients amenable to exon 51 skipping which is being evaluated in a Phase 1/2 clinical trial; SQY Therapeutics with SQY-51, a PMO for patients amenable to exon 51 skipping, which is also being evaluated in a Phase 1/2 clinical trial; NS Pharma, Inc. with NS-050/NCNP-03 and NS-089/NCNP-02, which are PMOs in Phase 1/2 and Phase 2 clinical trials for exon-50 and exon 44 skipping amenable DMD respectively; and Avidity with delpacibart zotadirsen (formerly known as AOC-1044), an antibody oligonucleotide conjugate for patients amenable to exon 44 skipping being evaluated in a Phase 1/2 clinical trial, which recently reported positive topline data and intent to file for accelerated approval with the FDA in 2026. In addition, gene therapies to treat DMD are in clinical development, including Solid Biosciences Inc. (SGT-003), REGENXBIO Inc. (RGX-202), Genethon (GNT-0004), and Insmed Inc. (INS1201). Gene editing treatments that are in preclinical development are also being pursued by Vertex and Sarepta. We are also aware of several companies targeting non-dystrophin mechanisms for the treatment of DMD.

There are currently no approved therapies to treat the underlying cause of DM1. Product candidates currently in clinical development to treat DM1 include: tideglusib, a GSK3-ß inhibitor in late-stage clinical development by AMO Pharma Ltd. for children and adults with DM1; pitolisant, a selective histamine 3 receptor antagonist / inverse agonist being evaluated in a Phase 2 clinical trial for non-muscular symptoms of DM1 by Harmony Biosciences Holdings, Inc.; delpacibart etedesiran (formerly AOC-1001), an antibody-linked siRNA being evaluated in a Phase 3 clinical trial by Avidity; PGN-EDODM1, a peptide-linked PMO, currently being evaluated in a Phase 1 clinical trial by Pepgen, Inc.; ARO-DM1, a peptide-linked siRNA being evaluated in a Phase 1/2a clinical trial in Australia and New Zealand by Arrowhead Pharmaceuticals, Inc.; ATX-01, a lipophilic peptide conjugated anti-miR designed to target microRNA 23b currently being evaluated in a Phase 1/2 clinical trial by ARTHEx Biotech S.L.; VX-670, an endosomal escape vehicle technology with a CUG steric blocker oligonucleotide by Entrada Therapeutics, Inc. in collaboration with Vertex being evaluated in a Phase 1/2 clinical trial in Canada, the United Kingdom, the European Union and Australia; SAR446268, an AAV-medicated gene therapy currently being evaluated in a Phase 1/2 clinical trial by Sanofi in the United States and Argentina; and JUV-161, an AKT-signaling activator currently in a Phase 1 single-ascending dose clinical trial in healthy volunteers by Juvena in Australia.

There are currently no therapies approved to treat FSHD. Products currently in development for FSHD include: ARO-DUX4, an siRNA therapy being evaluated in a Phase 3 clinical trial and licensed by Arrowhead Pharmaceuticals, Inc. to Sarepta; delpacibart braxlosiran (formerly AOC-1020), an antibody oligonucleotide conjugate being evaluated in a Phase 1/2 clinical trial by Avidity and RO7204239, an anti-latent myostatin antibody by Roche Pharmaceuticals that is in a Phase 2 clinical trial. Satralizumab, an anti-IL-6 antibody, is being evaluated in a Phase 2 clinical trial by the University Hospital of Nice. EpiCrispr Bio is developing an AAV-delivered CRISPR epigenome modification therapy targeting DUX4 that is currently in Phase 1/2 clinical trials. Scholar Rock Holding Corporation cleared its IND application for apitegromab in FSHD with Phase 2 study initiation and patient dosing expected mid-2026. Several other companies have therapies targeting DUX4 in preclinical development (e.g., Facio Biotherapies Pty Ltd, Kate Therapeutics Inc. (acquired by Novartis), Souffle Therapeutics, and Ionis).

There are three currently approved medicines for Pompe disease, all of which are enzyme replacement therapies: Myozyme/Lumizyme (alglucosidase alfa) and Nexviazyme/Nexviadyme (avalglucosidase alfa) by Sanofi, and Pombiliti + Opfolda (cipaglucosidase alfa-atga in combination with miglustat) by Amicus Therapeutics, Inc. Beyond these marketed products, the Pompe clinical pipeline consists of several clinical-stage product candidates that aim to address Pompe disease via alternative strategies. ACTUS-101, a gene therapy delivered to the liver for continuous, endogenous production of GAA currently being evaluated in a Phase 1/2 clinical trial by AskBio. AskBio, which is wholly owned by Bayer AG, also has its AB-1009 gene therapy program that is in a Phase 1/2 clinical trial in the United States for LOPD. AT-845 is a muscle-targeted gene therapy currently being evaluated in a Phase 1/2 clinical trial by Astellas Pharma US, Inc. for LOPD. In addition, ABX-1100 by ARO Biotherapeutics Co. and MZE-001 by Maze Therapeutics, Inc. are substrate reduction therapies in Phase 1 clinical trials. Denali Therapeutics, Inc. also announced plans to initiate a Phase 1 trial for its enzyme replacement therapy in January 2026.

We also expect to compete more generally with other companies developing alternative scientific and technological approaches to the treatment of muscle diseases, including other companies working to develop conjugates with oligonucleotides for extra-hepatic delivery, including Alnylam Pharmaceuticals, Inc., Aro Biotherapeutics, Inc., Arrowhead Pharmaceuticals, Inc., Avidity, Novo Nordisk A/S, DTx Pharma, Inc., Gennao Bio, Inc., Ionis and Sarepta, as well as gene therapy and gene editing approaches.

Many of the companies against which we compete or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Accordingly, our competitors may be more successful than us in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining approval for treatments and achieving widespread market acceptance, rendering our treatments obsolete or non-competitive.

Additionally, mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, more convenient, less expensive or marketed and sold more effectively than any products we may develop. Competitive products or technological approaches may make any products we develop, or our FORCE platform, obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

Even if any product candidate that we may develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community necessary for commercial success.

If any product candidate we may develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payers and others in the medical community. Sales of medical products depend in part on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe,

therapeutically effective and cost-effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our product is safe, therapeutically effective and cost-effective as compared with competing treatments. Efforts to educate the medical community and third-party payers on the benefits of any product candidates we may develop may require significant resources and may not be successful. If any product candidates we may develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any product candidates we may develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of such product candidates as demonstrated in clinical trials;
- the potential advantages and limitations compared to alternative treatments;
- the effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments;
- the clinical indications for which the product is approved;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products, if approved, together with other medications.

If the market opportunities for any product candidates we develop are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer. Because the target patient populations of our programs are small, and the addressable patient population even smaller, we must be able to successfully identify patients and capture a significant market share to achieve profitability and growth.

We focus our research and product development on treatments for rare diseases. Given the small number of patients who have the diseases that we are targeting, it is critical to our ability to grow and become profitable that we continue to successfully identify patients with these rare diseases. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with any product candidates we may develop, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics, patient foundations or market research that we conducted, and may prove to be incorrect or contain errors. New studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. The effort to identify patients with diseases we seek to treat is in early stages, and we cannot accurately predict the number of patients for whom treatment might be possible. Additionally, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business. Further, even if we obtain significant market share for our product candidates, because the potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

Our target patient populations are relatively small, and there is currently no standard of care treatment directed at some of our target indications, such as FSHD. As a result, the pricing and reimbursement of

any product candidates we may develop, if approved, is uncertain, but must be adequate to support commercial infrastructure. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell product candidates will be adversely affected.

The pricing, insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our future product candidates, if approved, could limit our ability to market those products and decrease our ability to generate product revenue.

The initial target platforms in our pipeline are indications with small patient populations. For product candidates that are designed to treat smaller patient populations to be commercially viable, the reimbursement for such product candidates must be higher, on a relative basis, to account for the lack of volume. Accordingly, we will need to implement a coverage and reimbursement strategy for any approved product candidate that accounts for the smaller potential market size. If we are unable to establish or sustain coverage and adequate reimbursement for any future product candidates from third-party payers, the adoption of those product candidates and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved.

We expect that coverage and reimbursement by third-party payers will be essential for most patients to be able to afford these treatments. Accordingly, sales of our future product candidates will depend substantially, both domestically and internationally, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or will be reimbursed by government authorities, private health coverage insurers and other third-party payers. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement by government authorities for new products are typically made by the Centers for Medicare & Medicaid Services, or CMS, since CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare. Private payers tend to follow CMS to a substantial degree. However, one payer's determination to provide coverage for a product does not assure that other payers will also provide coverage for the drug product. Further, a payer's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Reimbursement agencies in the European Union may be more conservative than CMS.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as any product candidates we may develop. In many countries, particularly the countries of the European Union, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay or might even prevent our commercial launch of the product, possibly for lengthy periods of time. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, the prices of products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for product candidates. Accordingly, in markets outside the United States, the reimbursement for any product candidates we may develop may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by governmental and third-party payers, in the United States and internationally, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for any product candidates we may develop. We expect to experience pricing pressures in connection with the sale of any product candidates we may develop due to the trend toward managed healthcare, the increasing influence of certain third-party payers, such as health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the healthcare market. There have been instances in which third-party payers have refused to reimburse treatments for patients for whom the treatment is indicated in the FDA-approved product label. Even if we are successful in obtaining FDA approvals to commercialize our product candidates, we cannot guarantee that we will be able to secure reimbursement for all patients for whom treatment with our product candidates is indicated.

In addition to CMS and private payers, professional organizations, such as the American Medical Association, can influence decisions about reimbursement for new products by determining standards for care. In addition, many private payers contract with commercial vendors who sell software that provide guidelines that attempt to limit utilization of, and therefore reimbursement for, certain products deemed to provide limited benefit to existing alternatives. Such organizations may set guidelines that limit reimbursement or utilization of our product candidates. Even if favorable coverage and reimbursement status is attained for one or more product candidates for which we or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

If we are unable to establish sales, marketing and distribution capabilities or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing any product candidates we may develop if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product for which we have obtained marketing approval, we will need to establish a sales, marketing and distribution organization, either ourselves or through collaborations or other arrangements with third parties.

In the future, we may build a sales and marketing infrastructure to market some of the product candidates we may develop if and when they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. These efforts may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales, marketing, coverage or reimbursement, customer service, medical affairs and other support personnel;
- the inability of sales personnel to educate adequate numbers of physicians on the benefits of any future products;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement and other acceptance by payers;
- the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability;
- restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own sales, marketing and distribution capabilities and we enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, are likely to be lower than if we were to market, sell and distribute any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute any product candidates we may develop or may be unable to do so on terms that are acceptable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing any product candidates we may develop.

The biologic product candidates for which we intend to seek approval may face competition sooner than anticipated.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Amendment, or the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. In December 2022, Congress clarified through FDORA that the FDA may approve multiple first interchangeable biosimilar biological products so long as the products are all approved on the first day on which such a product is approved as interchangeable with the reference product.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product.

There is a risk that any product candidates we may develop that are approved as a biological product under a BLA would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to U.S. congressional action or otherwise, or that the FDA will not consider any product candidates we may develop to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Further, the FDA may revise the standards governing approval of biosimilars so as to bring such products to the market more quickly. For example, in October 2025, the FDA issued draft guidance which proposes to eliminate the need for sponsors of biosimilar products to conduct comparative human clinical efficacy studies, allowing them to rely instead on analytical testing to demonstrate product differences from a reference product.

Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for nonbiological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Risks related to our intellectual property

If we or our licensors are unable to obtain, maintain and defend patent and other intellectual property protection for any product candidates or technology, or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully develop and commercialize any product candidates we may develop or our technology may be adversely affected due to such competition.

Our success depends in large part on our and our licensors' ability to obtain and maintain patent and other intellectual property protection in the United States and other jurisdictions. We currently own and license patents and patent applications relating to our FORCE platform technology, including our Fabs, payloads and Fab-payload conjugates, as well as aspects of our manufacturing and methods of treatment. We and our licensors have sought, and will seek, to protect our proprietary position by filing additional patent applications in the United States and abroad related to certain technologies and our platform that are important to our business. However, while much of our patent portfolio is at an early stage, we own 54 issued U.S. patents and fourteen granted foreign patents, and exclusively license three issued U.S. patents and one issued European patent. Moreover, there can be no assurance as to whether or when our patent applications will issue as granted patents. Our ability to stop third parties from making, using, selling, marketing, offering to sell, importing and commercializing any product candidates we may develop and our technology is dependent upon the extent to which we have rights under valid and enforceable patents and other intellectual property that cover our platform and technology. If we are unable to secure, maintain, defend and enforce patents and other intellectual property with respect to any product candidates we may develop and technology, it would have a material adverse effect on our business, financial condition, results of operations and prospects.

Our pending Patent Cooperation Treaty, or PCT, patent applications are not eligible to become issued patents until, among other things, we file a national stage patent application within 30 to 32 months, depending on the jurisdiction, from such application's priority date in the jurisdictions in which we are seeking patent protection. Similarly, our pending provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of such provisional patent application's filing date. If we do not timely file such national stage patent applications or non-provisional patent applications, we may lose our priority date with respect to such PCT or provisional patent applications, respectively, and any patent protection on the inventions disclosed in such PCT or provisional patent applications, respectively. While we and our licensors intend to timely file selected national stage and non-provisional patent applications relating to our PCT and provisional patent applications, respectively, we cannot predict whether any such patent applications will result in the issuance of patents. If we or our licensors do not successfully obtain issued patents, or, if the scope of any patent protection we or our licensors obtain is not sufficiently broad, we will be unable to prevent others from using any product candidates we may develop or our technology or from developing or commercializing technology and products similar or identical to ours or other competing products and technologies. Any failure to obtain or maintain patent protection with respect to our product candidates or our FORCE platform would have a material adverse effect on our business, financial condition, results of operations and prospects.

The patent prosecution process is expensive, time-consuming and complex, and we and our licensors may not be able to file, prosecute, maintain, defend, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. We and our licensors may not be able to obtain, maintain or defend patents and patent applications due to the subject matter claimed in such patents and patent applications being in the public domain. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Consequently, we would not be able to prevent any third party from using any of our technology that is in the public domain to compete with any product candidates we may develop.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of patent rights are highly uncertain. Our pending and future owned and licensed patent applications may not result in patents being issued which protect our technology or product candidates, effectively prevent others from commercializing competitive technologies and product or otherwise provide any competitive advantage.

In fact, patent applications may not issue as patents at all, and even if such patent applications do issue as patents, they may not issue in a form, or with a scope of claims, that will provide us with any meaningful protection, prevent others from competing with us or otherwise provide us with any competitive advantage. In addition, the scope of claims of an issued patent can be reinterpreted after issuance, and changes in either the patent laws or interpretation of the patent laws in the United States and other jurisdictions may diminish the value of our patent rights or narrow the scope of our patent protection. Furthermore, our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Third parties have developed technologies that may be related or competitive to our own technologies and product candidates and may have filed or may file patent applications, or may have obtained issued patents, claiming inventions that may overlap or conflict with those claimed in our owned or licensed patent applications or issued patents. We may not be aware of all third-party intellectual property rights potentially relating to our current and future product candidates and technology. Publications of discoveries in the scientific literature often lag the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know for certain whether the inventors of our owned or licensed patents and patent applications were the first to make the inventions claimed in any owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. If a third party can establish that we or our licensors were not the first to make or the first to file for patent protection of such inventions, our owned or licensed patent applications may not issue as patents and even if issued, may be challenged and invalidated or ruled unenforceable.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and other jurisdictions. For example, we may be subject to a third-party submission of prior art to the United States Patent and Trademark Office, or USPTO, challenging the validity of one or more claims of our owned or licensed patents. Such submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on one of our owned or licensed pending patent applications. We may become involved in opposition, derivation, re-examination, *inter partes* review, post-grant review or interference proceedings and similar proceedings in foreign jurisdictions (for example, opposition proceedings) challenging our owned or licensed patent rights. In addition, a third party may claim that our owned or licensed patent rights are invalid or unenforceable in a litigation. An adverse result in any litigation or patent office proceeding could put one or more of our owned or licensed patents at risk of being invalidated, ruled unenforceable or interpreted narrowly and could allow third parties to commercialize products identical or similar to any product candidates we may develop and compete directly with us, without payment to us. Moreover, we, or one of our licensors, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such challenges and proceedings may result in loss of patent rights, exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and any product candidates we may develop. Such challenges and proceedings may also result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Moreover, there could be public announcements of the results of hearings, motions or other interim proceedings or developments related to such challenges and proceedings. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Furthermore, patents have a limited lifespan. In the United States, the expiration of a patent is generally 20 years from the earliest date of filing of the first non-provisional patent application to which the patent claims priority. Patent term adjustments and extensions may be available; however, the overall term of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent and other intellectual property rights may not provide us with sufficient rights to

exclude others from commercializing products similar or identical to our technology and any product candidates we may develop. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Our rights to develop and commercialize any product candidates are subject and may in the future be subject, in part, to the terms and conditions of licenses granted to us by third parties. If we fail to comply with our obligations under our current or future intellectual property license agreements or otherwise experience disruptions to our business relationships with our current or any future licensors, we could lose intellectual property rights that are important to our business.

We are and expect to continue to be reliant upon third-party licensors for certain patent and other intellectual property rights that are important or necessary to the development of our technology and product candidates. For example, we are party to a license from the UMONS to certain patent rights and know-how of UMONS. Our license agreement with UMONS imposes, and we expect that any future license agreement will impose, specified diligence, milestone payment, royalty, commercialization, development and other obligations on us and require us to meet development timelines, or to exercise diligent or commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. For more information on the terms of the license agreement with UMONS, see Item 1. “Business—Intellectual Property—License Agreement with the University of Mons” in this Annual Report on Form 10-K.

Furthermore, our licensors have, or may in the future have, the right to terminate a license if we materially breach the agreement and fail to cure such breach within a specified period or in the event we undergo certain bankruptcy events. In spite of our best efforts, our current or any future licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements. If our license agreements are terminated, we may lose our rights to develop and commercialize product candidates and technology, lose patent protection, experience significant delays in the development and commercialization of our product candidates and technology, and incur liability for damages. If these in-licenses are terminated, or if the underlying intellectual property fails to provide the intended exclusivity, our competitors or other third parties could have the freedom to seek regulatory approval of, and to market, products and technologies identical or competitive to ours and we may be required to cease our development and commercialization of certain of our product candidates and technology. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties, including our competitors, to receive licenses to a portion of the intellectual property that is subject to our existing licenses and to compete with any product candidates we may develop and our technology. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our or our licensors’ ability to obtain, maintain and defend intellectual property and to enforce intellectual property rights against third parties;
- the extent to which our technology, product candidates and processes infringe, misappropriate or otherwise violate the intellectual property of the licensor that is not subject to the license agreement;
- the sublicensing of patent and other intellectual property rights under our license agreements;
- our diligence, development, regulatory, commercialization, financial or other obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our current or future licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, our license agreement with UMONS is, and future license agreements are likely to be, complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our diligence, development, regulatory, commercialization, financial or other obligations under the relevant agreement. In addition, if disputes over intellectual property that we have licensed or any other dispute related to our license agreements prevent or impair our ability to maintain our current license agreements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates and technology. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

License agreements we may enter into in the future may be non-exclusive. Accordingly, third parties may also obtain non-exclusive licenses from such licensors with respect to the intellectual property licensed to us under such license agreements. Accordingly, these license agreements may not provide us with exclusive rights to use such licensed patent and other intellectual property rights, or may not provide us with exclusive rights to use such patent and other intellectual property rights in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and any product candidates we may develop in the future.

Moreover, some of our in-licensed patent and other intellectual property rights may in the future be subject to third party interests such as co-ownership. If we are unable to obtain an exclusive license to such third-party co-owners' interest, in such patent and other intellectual property rights, such third-party co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. We or our licensors may need the cooperation of any such co-owners of our licensed patent and other intellectual property rights in order to enforce them against third parties, and such cooperation may not be provided to us or our licensors.

Additionally, we may not have complete control over the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications that we license from third parties. It is possible that our licensors' filing, prosecution and maintenance of the licensed patents and patent applications, enforcement of patents against infringers or defense of such patents against challenges of validity or claims of enforceability may be less vigorous than if we had conducted them ourselves, and accordingly, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our licensors fail to file, prosecute, maintain, enforce and defend such patents and patent applications, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, our right to develop and commercialize any of our technology and any product candidates we may develop that are the subject of such licensed rights could be adversely affected and we may not be able to prevent competitors or other third parties from making, using and selling competing products.

Furthermore, our owned and in-licensed patent rights may be subject to a reservation of rights by one or more third parties. When new technologies are developed with government funding, in order to secure ownership of patent rights related to the technologies, the recipient of such funding is required to comply with certain government regulations, including timely disclosing the inventions claimed in such patent rights to the U.S. government and timely electing title to such inventions. A failure to meet these obligations may lead to a loss of rights or the unenforceability of relevant patents or patent applications. In addition, the U.S. government may have certain rights in such patent rights, including a non-exclusive license authorizing the U.S. government to use the invention or to have others use the invention on its behalf. If the U.S. government decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. The U.S. government's rights may also permit it to disclose the funded inventions and technology, which may include our confidential information, to third parties and to exercise march-in rights to use or allow third parties to use the technology that was developed using U.S. government funding. The U.S. government may exercise its march-in rights if it determines that action is necessary because we or our licensors failed to achieve practical application of the U.S. government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements

of federal regulations, or to give preference to U.S. industry. In addition, our rights in such U.S. government-funded inventions may be subject to certain requirements to manufacture any product candidates we may develop embodying such inventions in the United States. Any of the foregoing could harm our business, financial condition, results of operations and prospects significantly.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, maintaining, enforcing and defending patents and other intellectual property rights on our technology and any product candidates we may develop in all jurisdictions throughout the world would be prohibitively expensive, and accordingly, our intellectual property rights in some jurisdictions outside the United States could be less extensive than those in the United States. In some cases, we or our licensors may not be able to obtain patent or other intellectual property protection for certain technology and product candidates outside the United States. In addition, the laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we and our licensors may not be able to obtain issued patents or other intellectual property rights covering any product candidates we may develop and our technology in all jurisdictions outside the United States and, as a result, may not be able to prevent third parties from practicing our and our licensors' inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Third parties may use our technologies in jurisdictions where we and our licensors have not pursued and obtained patent or other intellectual property protection to develop their own products and, further, may export otherwise infringing, misappropriating or violating products to territories where we have patent or other intellectual property protection, but enforcement is not as strong as that in the United States. These products may compete with any product candidates we may develop and our technology and our or our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Additionally, many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain jurisdictions, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement, misappropriation or other violation of our patent and other intellectual property rights or marketing of competing products in violation of our intellectual property rights generally. For example, an April 2019 report from the Office of the United States Trade Representative identified a number of countries, including China, Russia, Argentina, Chile and India, where challenges to the procurement and enforcement of patent rights have been reported. Proceedings to enforce our or our licensors' patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patent and other intellectual property rights at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We or our licensors may not prevail in any lawsuits that we or our licensors initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

As another example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system went into effect on June 1, 2023, which significantly impacts European patents, including those granted before the introduction of such system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (UPC). Existing European patents and published applications may be opted out of the jurisdiction of the UPC at any time before the end of a transitional period (at least seven years from the UPC Agreement which went into effect on June 1, 2023), unless an action has already been brought before the UPC in which case an opt-out request cannot be filed. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single

UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

Many jurisdictions have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many jurisdictions limit the enforceability of patents against government agencies or government contractors. In these jurisdictions, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or patent applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patent rights. We rely on our outside counsel and other professionals or our licensing partners to pay these fees due to the USPTO and non-U.S. government patent agencies. The USPTO and various non-U.S. government patent agencies also require compliance with several procedural, documentary and other similar provisions during the patent application process. We rely on our outside counsel and other professionals to help us comply and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment, loss of priority or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

We may not be successful in obtaining necessary rights to product candidates we may develop through acquisitions and in-licenses.

We currently have rights to certain intellectual property through licenses from third parties. Because our product candidates may require the use of additional intellectual property rights held by third parties, the growth of our business likely will depend, in part, on our ability to acquire, in-license or use these intellectual property rights. In addition, with respect to any patent or other intellectual property rights that we co-own with third parties, we may require exclusive licenses to such co-owners' interest in such patent or other intellectual property rights. However, we may be unable to secure such licenses or otherwise acquire or in-license any intellectual property rights related to compositions, methods of use, processes or other components from third parties that we identify as necessary for any product candidates we may develop and our technology on commercially reasonable terms, or at all. Even if we are able to in-license any such necessary intellectual property, it could be on non-exclusive terms, thereby giving our competitors and other third parties access to the same intellectual property licensed to us, and the applicable licensors could require us to make substantial licensing and royalty payments. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

We sometimes collaborate with non-profit and academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us

with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to third parties, potentially blocking our ability to pursue our research program and develop and commercialize our product candidates.

If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have licensed, we may be required to expend significant time and resources to redesign any product candidates we may develop or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Issued patents covering any product candidates we may develop could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

Our owned and licensed patent rights may be subject to priority, validity, inventorship and enforceability disputes. If we or our licensors are unsuccessful in any of these proceedings, such patent rights may be narrowed, invalidated or held unenforceable, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or we may be required to cease the development, manufacture and commercialization of one or more of our product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we or one of our licensors initiate legal proceedings against a third party to enforce a patent covering any of the product candidates we may develop or our technology, the defendant could counterclaim that the patent covering the product candidate or technology is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Third parties also may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, interference proceedings, derivation proceedings, post grant review, *inter partes* review and equivalent proceedings such as opposition, invalidation and revocation proceedings in foreign jurisdictions. Such proceedings could result in the revocation or cancellation of or amendment to our patents in such a way that they no longer cover any product candidates we may develop or our technology or prevent third parties from competing with any product candidates we may develop or our technology. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which the patent examiner and we or our licensing partners were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection on one or more of our product candidates or technology. Such a loss of patent protection could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect and some courts inside and outside the United States are less willing or unwilling to protect trade secrets. We seek to protect our

proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, contractors and other parties who have access to such technology and processes. However, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees and consultants who are parties to these agreements breach or violate the terms of any of these agreements, we may not have adequate remedies for any such breach or violation. In such circumstances, third parties could potentially use our trade secrets to compete with any product candidates we may develop and our technology. Additionally, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems; however, such systems and security measures may be breached, and we may not have adequate remedies for any breach.

In addition, our trade secrets may otherwise become known or be independently discovered by competitors or other third parties. Competitors or third parties could purchase any product candidates we may develop or our technology and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our intellectual property rights or develop their own competitive technologies that fall outside the scope of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate such trade secrets, from using that technology or information to compete with us. If our trade secrets are not adequately protected so as to protect our market against competitors' products, our business, financial condition, results of operations and prospects could be materially and adversely affected.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could harm our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. We may become party to, or be threatened with, adversarial proceedings or litigation in which third parties may assert infringement, misappropriation or other violation claims against us, alleging that any product candidates we may develop, manufacturing methods, formulations or administration methods are covered by their patents. Given the vast number of patents and other intellectual property in our field of technology, we cannot be certain or guarantee that we do not infringe, misappropriate or otherwise violate patents or other intellectual property. Other companies and institutions have filed, and continue to file, patent applications that may be related to our technology and, more broadly, to gene therapy and related manufacturing methods. Some of these patent applications have already been allowed or issued and others may issue in the future. Since this area is competitive and of strong interest to pharmaceutical and biotechnology companies, there will likely be additional patent applications filed and additional patents granted in the future, as well as additional research and development programs expected in the future. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that we may be subject to claims of infringement of the patent rights of third parties. If a patent holder believes the manufacture, use, sale or importation of any product candidates we may develop or our technology infringes its patent, the patent holder may sue us even if we have licensed other patent rights for our technology.

We are aware of certain patents in the United States and other jurisdictions owned by third parties that claim subject matter that relates to our program candidates and the FORCE platform. Although we believe that these patents are invalid and/or not infringed, such third parties may assert these patents against us in litigation in the United States or other jurisdictions. The outcome of any such litigation is uncertain and, even if we prevail, the costs of such litigation could have a material adverse effect on our financial position, result in disclosure of our trade secrets, distract key personnel from the continued development of our business, and adversely affect our ability to enter or maintain commercial relationships with collaborators, clients or customers. If we are unsuccessful in such litigation, we could be prevented from commercializing products or could be required to take licenses from such third parties which may not be available on commercially reasonable terms, if at all.

It is also possible that we have failed to identify relevant third-party patents or applications. Because patent applications can take many years to issue, may be confidential for 18 months or more after filing and can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use, sale or importation of any product candidates we may develop or our technology and we may not be aware of such patents. Furthermore, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States may remain confidential until a patent issues. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to any product candidates we may develop and our technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. In addition, we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, any product candidates we may develop or the use of any product candidates we may develop.

Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could adversely affect our ability to commercialize any product candidates we may develop or any other of our product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing any product candidates we may develop and our technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product candidates. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing any product candidates we may develop or force us to cease some of our business operations, which could harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

Intellectual property litigation or other proceedings could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Competitors may challenge the validity and enforceability of our patent rights or those of our licensing partners, infringe, misappropriate or otherwise violate our or our licensors' patent and other intellectual property rights, or we may be required to defend against claims of infringement, misappropriation or other violation. Litigation and other proceedings in connection with any of the foregoing claims can be unpredictable, expensive and time consuming. Even if resolved in our favor, litigation or other proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our scientific, technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors or other third parties may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could adversely affect our ability to compete in the marketplace and could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or be required to obtain licenses to such intellectual property rights, which may not be available on commercially reasonable terms or at all. An inability to incorporate such intellectual property rights would harm our business and may prevent us from successfully commercializing any product candidates we may develop or at all. In addition, we may lose personnel as a result of such claims and any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize any product candidates we may develop and our technology, which would have a material adverse effect on our business, results of operations, financial condition and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our scientific and management personnel.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. Moreover, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Furthermore, individuals executing agreements with us may have pre-existing or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual.

Disputes about the ownership of intellectual property that we own may have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, we or our licensors may in the future be subject to claims by former employees, consultants or other third parties asserting an ownership right in our owned or licensed patent rights. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar technology and therapeutics, without payment to us, or could limit the duration of the patent protection covering our technology and any product candidates we may develop. Such challenges may also result in our inability to develop, manufacture or commercialize our technology and product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our owned or licensed patent rights are threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future technology and product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop and our technology, one or more of our U.S. patents that we license or may own in the future may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved product, a method for using it or a method for manufacturing it may be extended. The application for the extension must be submitted prior to the expiration of the patent for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims challenging the inventorship or ownership of our patent and other intellectual property rights.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patent rights, trade secrets or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates or technology. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patent rights, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of or right to use intellectual property that is important to any product candidates we may develop or our technology. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We have filed trademark applications with the USPTO for our corporate name, logos and tagline and have filed trademark applications in foreign jurisdictions. Our current and future trademark applications in the United States and other foreign jurisdictions may not be allowed or may be subsequently opposed. Once filed and registered, our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive and time-consuming, particularly for a company of our size. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations or prospects.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to any product candidates we may develop but that are not covered by the intellectual property, including the claims of the patents, that we own or license currently or in the future;
- we, or our license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or license currently or in the future;
- we, or our license partners or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our owned or licensed intellectual property rights;
- it is possible that our or our licensors' current or future pending patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by third parties;
- third parties might conduct research and development activities in jurisdictions where we do not have patent or other intellectual property rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents or other intellectual property rights of others may have an adverse effect on our business; and
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could significantly harm our business, financial condition, results of operations and prospects.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor or other third party will discover our trade secrets or that our trade secrets will be misappropriated or disclosed.

Because we currently rely on certain third parties to manufacture all or part of our drug product and to perform quality testing, and because we collaborate with various organizations and academic institutions for the advancement of our product engine and pipeline, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements and other similar agreements with our collaborators, advisors, employees, consultants and contractors prior to beginning research or disclosing any proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors or other third parties, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets by third parties. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's or other third party's discovery of our proprietary technology and confidential information or other unauthorized use or disclosure would impair our competitive position and may harm our business, financial condition, results of operations and prospects.

Risks related to regulatory approval and other regulatory and legal compliance matters

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of any product candidates we may develop. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, product candidates we may develop, and our ability to generate revenue will be materially impaired.

Any product candidates we may develop and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate we may develop will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction. We have no experience as a company in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety, purity and potency. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we may develop may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities, or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Of the large number of products in development, only a small percentage

successfully complete the FDA or foreign regulatory approval processes and are commercialized. Even if any product candidates we may develop demonstrate safety and efficacy in clinical trials, the regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired.

Further, under the Pediatric Research Equity Act, or PREA, a new drug application, or NDA, a BLA or supplement to an NDA or BLA for certain drugs and biological products must contain data to assess the safety and effectiveness of the drug or biological product in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless the sponsor receives a deferral or waiver from the FDA. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric trials begin. The applicable legislation in the European Union also requires sponsors to either conduct clinical trials in a pediatric population in accordance with a Pediatric Investigation Plan approved by the Pediatric Committee of the EMA, or to obtain a waiver or deferral from the conduct of these studies by the Pediatric Committee of the EMA. For any of our product candidates for which we seek regulatory approval in the United States or the European Union, we cannot guarantee that we will be able to obtain a waiver or alternatively complete any required studies and other requirements in a timely manner, or at all, which could result in associated reputational harm and subject us to enforcement action.

Moreover, principal investigators for our future clinical trials may serve as scientific advisors or consultants to us and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or a comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

Even if we eventually complete clinical testing and receive approval of a BLA or foreign marketing application for any product candidates, the FDA or the comparable foreign regulatory authority may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-market clinical trials. The FDA or the comparable foreign regulatory authority also may approve or authorize for marketing a product candidate for a more limited indication or patient population that we originally request, and the FDA or comparable foreign regulatory authority may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any of these restrictions or commitments could render an approved product not commercially viable, which would materially adversely impact our business and prospects.

In addition, we could be adversely affected by several significant administrative law cases decided by the U.S. Supreme Court in 2024. In *Loper Bright Enterprises v. Raimondo*, for example, the court overruled *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc*., which for 40 years required federal courts to defer to permissible agency interpretations of statutes that are silent or ambiguous on a particular topic. The U.S. Supreme Court stripped federal agencies of this presumptive deference and held that courts must exercise their independent judgment when deciding whether an agency, such as the FDA, acted within its statutory authority under the Administrative Procedure Act, or APA. Additionally, in *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, the U.S. Supreme Court held that actions to challenge a federal regulation under the APA can be initiated within six years of the date of injury to the plaintiff, rather than the date the rule is finalized. The decision appears to give prospective plaintiffs a personal statute of limitations to challenge longstanding agency regulations. Another decision, *Securities and Exchange Commission v. Jarkesy*, overturned regulatory agencies' ability to impose civil penalties in administrative proceedings. These decisions could introduce additional uncertainty into the regulatory process and may result in additional legal challenges to actions taken by federal regulatory agencies, including the FDA and CMS, that we rely on. In addition to potential changes to regulations as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays and other impacts, any of which could adversely impact our business and operations.

In addition, our ability to develop and market new drug products may be impacted by litigation challenging the FDA's approval of mifepristone. In April 2023, the U.S. District Court for the Northern District of Texas invalidated the approval by the FDA of mifepristone, a drug product which was originally approved in 2000 and whose distribution is governed by various measures adopted under a Risk Evaluation and Mitigation Strategy. On appeal, the U.S. Court of Appeals for the Fifth Circuit held that plaintiffs were likely to prevail in their claim that changes allowing for expanded access of mifepristone that FDA authorized in 2016 and 2021 were arbitrary and capricious and in violation of federal law. In June 2024, the U.S. Supreme Court reversed and remanded that decision after unanimously finding that the plaintiffs did not have standing to bring this legal action against the FDA. Thereafter, the Attorneys General of three states filed an amended complaint in the district court in Texas challenging the FDA's actions. On September 30, 2025, the district court declined to dismiss the case and, instead, transferred it to the federal district court in the Eastern District of Missouri. Depending on the outcome of this litigation, if it continues, our ability to develop new drug product candidates and to maintain approval of any then-existing drug products could be at risk and could be delayed, undermined or subject to protracted litigation.

We, or any future collaborator, may seek approval from the FDA or comparable foreign regulatory authorities to use accelerated development pathways for our product candidates. If we, or any future collaborator, are not able to use such pathways, we, or they, may be required to conduct additional clinical trials beyond those that are contemplated, which would increase the expense of obtaining, and delay the receipt of, necessary marketing approvals, if we, or they, receive them at all. In addition, even if an accelerated approval pathway is available to us, or any future collaborator, it may not lead to expedited approval of our product candidates, or approval at all.

We are currently pursuing accelerated development pathways for our product candidates for DM1 and DMD. Under the Federal Food, Drug and Cosmetic Act, or FDCA, and implementing regulations, the FDA may grant accelerated approval to a product candidate to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies, upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a

direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. Similar risks to those described above are also applicable to any application that we, or any future collaborator, may submit in jurisdictions outside of the United States. Prior to seeking such accelerated approval, we, or any future collaborator, may continue to seek feedback from the FDA or comparable foreign regulatory agencies and otherwise evaluate our, or their, ability to seek and receive such accelerated approval.

There can be no assurance that the FDA or foreign regulatory agencies will agree with our, or any future collaborators', surrogate endpoints or intermediate clinical endpoints in any of our, or their, clinical trials, or that we, or future collaborator, will decide to pursue or submit any additional BLAs for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that, after feedback from the FDA or comparable foreign regulatory agencies, we, or any future collaborator, will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval. Furthermore, for any submission of an application for accelerated approval or application under another expedited regulatory designation, there can be no assurance that such submission or application will be accepted for filing or that any expedited development, review or approval will be granted on a timely basis, or at all.

Finally, there can be no assurance that we will satisfy all FDA requirements, including new provisions, that govern accelerated approval. For example, with passage of the FDORA in December 2022, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation authorized the FDA to require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded and to submit progress reports on its post-approval studies to FDA every six months until the study is completed. Moreover, FDORA established expedited procedures authorizing FDA to withdraw an accelerated approval if certain conditions are met, including where a required confirmatory study fails to verify and describe the predicted clinical benefit or where evidence demonstrates the product is not shown to be safe or effective under the conditions of use. The FDA may also use such procedures to withdraw an accelerated approval if a sponsor fails to conduct any required post-approval study of the product with due diligence, including with respect to "conditions specified by the Secretary." The new procedures include the provision of due notice and an explanation for a proposed withdrawal, and opportunities for a meeting with the Commissioner or the Commissioner's designee and a written appeal, among other things. We will need to fully comply with these and other requirements in connection with the development and approval of any product candidate that qualifies for accelerated approval.

In March 2023, the FDA issued draft guidance that outlines its current thinking and approach to accelerated approval. The FDA indicated that the accelerated approval pathway is commonly used for approval of oncology drugs due to the serious and life-threatening nature of cancer. Although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach as it provides a more robust efficacy and safety assessment and allows for direct comparisons to an available therapy. To that end, the FDA outlined considerations for designing, conducting, and analyzing data for trials intended to support accelerated approvals of oncology therapeutics. Subsequently, in December 2024 and January 2025, the FDA issued additional draft guidances relating to accelerated approval. While these guidances are currently only in draft form and will ultimately not be legally binding even when finalized, we will need to observe the FDA's guidances closely to ensure that our products qualify for accelerated approval.

Accordingly, a failure to obtain and maintain accelerated approval or any other form of expedited development, review or approval for our product candidates, or withdrawal of a product candidate, would result in a longer time period until commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

Obtaining and maintaining marketing approval or commercialization of our product candidates in the United States does not mean that we will be successful in obtaining marketing approval of our product candidates in other jurisdictions. Failure to obtain marketing approval in foreign

jurisdictions would prevent any product candidates we may develop from being marketed in such jurisdictions, which, in turn, would materially impair our ability to generate revenue.

In order to market and sell any product candidates we may develop in the European Union and many other foreign jurisdictions, we or our collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or these third parties may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our medicines in any jurisdiction, which would materially impair our ability to generate revenue.

Additionally, we could face heightened risks with respect to obtaining marketing authorization in the United Kingdom as a result of the withdrawal of the United Kingdom from the European Union, commonly referred to as Brexit. The United Kingdom is no longer part of the European Single Market and EU Customs Union. As of January 1, 2025, the MHRA is responsible for approving all medicinal products destined for the United Kingdom market (i.e., Great Britain and Northern Ireland). On April 28, 2025, the U.K. Parliament adopted amendments to improve and strengthen the U.K.'s clinical trials regulatory regime; they will take effect on April 28, 2026. These changes were needed since the current U.K. requirements are based upon the now-repealed EU Clinical Trials Directive (2001/20/EC), which has been replaced by the European Clinical Trials Regulation (Regulation EU No 536/2014). Since the United Kingdom left the European Union prior to the date on which the EU CTR took effect, the UK legal framework did not benefit from the same revisions as occurred at EU level.

Further, as of January 1, 2025, a new international recognition procedure, or IRP, will apply, which intends to facilitate approval of pharmaceutical products in the UK. The IRP is open to applicants that have already received an authorization for the same product from one of the MHRA's specified Reference Regulators, or RRs. The RRs notably include EMA and regulators in the EU/European Economic Area, or EEA, member states for approvals in the EU centralized procedure and mutual recognition procedure as well as the FDA (for product approvals granted in the United States). However, the concrete functioning of the IRP is currently unclear. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us or our collaborators to restrict or delay efforts to seek regulatory approval in the UK for our product candidates, which could significantly and materially harm our business.

In addition, foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products was published in April 2023. On June 4, 2025, after almost two years of negotiations among the EU Member States, the Council of the European Union adopted its position on the proposed overhaul of the EU general pharmaceutical legislative framework, which is known as the new Pharma Package. Thereafter, on December 11, 2025, the European Parliament and Council reached a provisional political agreement on the legislation which is expected to be adopted by mid-2026. The revisions may have a significant impact on the pharmaceutical industry and our business. They would, among other things, set a baseline period of 8 years of data exclusivity and one year of market exclusivity with possible extensions for new indications up to a maximum of 11 years total. There will likely be a transition period, with the changes taking effect in mid-2028.

Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of the Trade and Cooperation Agreement or otherwise, would prevent us from commercializing any product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or the European Union for any product candidates we may develop, which could significantly and materially harm our business.

We are conducting and intend to conduct certain of our clinical trials globally. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We are conducting and intend to continue conducting certain of our clinical trials globally. The acceptance by the FDA or other regulatory authorities of study data from clinical trials conducted outside their jurisdiction may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to cGCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the clinical trial is well-designed and well-conducted in accordance with cGCP requirements and the FDA is able to validate the data from the trial through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with additional foreign regulatory requirements; foreign exchange fluctuations; compliance with foreign manufacturing, customs, shipment and storage requirements; cultural differences in medical practice and clinical research; diminished protection of intellectual property in some countries; and interruptions or delays in our trials resulting from geopolitical events, such as war or terrorism.

Fast Track designation by the FDA may not actually lead to a faster development or regulatory review or approval process and does not assure FDA approval of any product candidates we may develop.

If any product candidate we may develop is intended for the treatment of a serious or life-threatening condition and the product candidate demonstrates the potential to address unmet medical need for this condition, we may apply for FDA Fast Track designation. In October 2022, the FDA granted Fast Track designation for z-rostudirsen, and in January 2025, the FDA granted Fast Track designation for z-basivarsen. However, a Fast Track designation does not ensure that the product candidate will receive marketing approval or that approval will be granted within any particular timeframe. As a result, while we may seek and receive Fast Track designation for any product candidates we may develop, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA’s priority review procedures.

Breakthrough or RMAT therapy designation by the FDA may not lead to a faster regulatory review or approval process and, in any event, does not assure FDA approval of any product candidates we may develop.

If any product candidate we may develop is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development, the sponsor may apply for FDA breakthrough designation or a regenerative medicine advanced therapy, or RMAT, designation. In June 2025, the FDA granted Breakthrough Therapy Designation to z-basivarsen for the treatment of DM1. Additionally, in August 2025, the FDA granted Breakthrough Therapy Designation to z-rostudirsen for the treatment of DMD, amenable to exon 51 skipping. However, neither a breakthrough designation nor an RMAT designation ensures that the product candidate will receive marketing approval or that approval will be granted within any particular timeframe. As a result, while we may seek and receive breakthrough or RMAT designation for any product candidates we may develop, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw breakthrough or RMAT designation if it believes that the designation is no longer supported by data from our clinical development program. Neither breakthrough nor RMAT designation alone guarantees qualification for the FDA's priority review procedures.

Priority review designation by the FDA may not lead to a faster regulatory review or approval process and, in any event, does not assure FDA approval of any product candidates we may develop.

If the FDA determines that a product candidate we may develop offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review for any product candidates we may develop, and our expectations regarding the timelines for potential commercial launches of z-rostudirsen and z-basivarsen contemplate their receipt of priority review by the FDA. However, the FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate we may develop is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily mean a faster regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or thereafter.

On June 17, 2025, the FDA announced the creation of a new voucher program to expedite the development and approval of new drug products. Vouchers issued under the new program, which is known as the Commissioner's National Priority Voucher, or CNPV, Program, may reportedly be redeemed by sponsors to shorten the review time of a BLA from approximately 10 to 12 months to 1 to 2 months. The FDA has indicated that the new CNPV process will convene experts from the FDA's offices for a team-based review rather than using the standard review system of a drug application being sent to numerous FDA offices. Clinical information will be reviewed by a multidisciplinary team of physicians and scientists who will pre-review the submitted information and convene for a 1-day meeting. Vouchers under this program will reportedly be given to companies aligned with U.S. national priorities. On October 16, 2025, the FDA announced nine voucher recipients under the CNPV Program.

We may not be able to obtain orphan drug exclusivity for product candidates we may develop, and even if we do, that exclusivity may not prevent regulatory authorities from approving other competing products.

In March 2023 and April 2025, respectively, the EMA and FDA granted orphan drug designation to z-rostudirsen for the treatment of DMD in patients amenable to exon 51 skipping. In May and September 2023, respectively, the EMA and FDA granted orphan drug designation to z-basivarsen for the treatment of DM1. Additionally, in January 2026, the Ministry of Health, Labour and Welfare in Japan also granted

orphan drug designation to z-basivarsen for the treatment of DM1. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition. A similar regulatory scheme governs approval of orphan products by the EMA in the European Union. Generally, if a product candidate with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same product for the same therapeutic indication for that time period. The applicable period is seven years in the United States and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if a product no longer meets the criteria for orphan drug designation, in particular if the product is sufficiently profitable so that market exclusivity is no longer justified.

In order for the FDA to grant orphan drug exclusivity to one of our products, the agency must find that the product is indicated for the treatment of a condition or disease with a patient population of fewer than 200,000 individuals annually in the United States. The FDA may conclude that the condition or disease for which we seek orphan drug exclusivity does not meet this standard. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition. In particular, the concept of what constitutes the "same drug" for purposes of orphan drug exclusivity remains in flux in the context of gene therapies, and the FDA has issued recent draft guidance suggesting that it would not consider two genetic medicine products to be different drugs solely based on minor differences in the transgenes or vectors. In addition, even after an orphan drug is approved, the FDA can subsequently approve the same product for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity may also be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition.

In 2017, the U.S. Congress passed the FDA Reauthorization Act of 2017, or the FDARA. FDARA, among other things, codified the FDA's pre-existing regulatory interpretation, to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The new legislation reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority.

The FDA and the U.S. Congress may further reevaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals for the 11th Circuit (*Catalyst Pharms., Inc. v. Becerra)* in September 2021 finding that, for the purpose of determining the scope of exclusivity, the term "same disease or condition" means the designated "rare disease or condition" and could not be interpreted by the FDA to mean the "indication or use." Thus, the court concluded, orphan drug exclusivity applies to the entire designated disease or condition rather than the "indication or use." Although there have been legislative proposals to overrule this decision, they have not been enacted into law. On January 23, 2023, the FDA announced that, in matters beyond the scope of that order, the FDA will continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug was approved. In February 2025, a federal district court in Washington, D.C. fully embraced the reasoning in the 11th Circuit decision in another court decision (*Neurelis v. Brenner*) challenging the scope of orphan drug exclusivity. On April 17, 2025, the FDA appealed this decision to the U.S. Court of Appeals for the D.C. Circuit. The implications of this decision, and its impact on the FDA's implementation of the Orphan Drug Act, are unclear at this point.

Even if we, or any collaborators we may have, obtain marketing approvals for any product candidates we may develop, the terms of approvals and ongoing regulation of our products could require the substantial expenditure of resources and may limit how we, or they, manufacture and market our products, which could materially impair our ability to generate revenue.

Any product candidate for which we obtain marketing approval, if ever, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such medicine, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The FDA typically advises that patients treated with genetic medicine undergo follow-up observations for potential adverse events for a 15-year period. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the medicine may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine. Similar restrictions apply to the approval of products in the European Union.

Accordingly, assuming we, or any third parties we may collaborate with, receive marketing approval for one or more product candidates we may develop, we, and such collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we and such collaborators are not able to comply with post-approval regulatory requirements, we and such collaborators could have the marketing approvals for our products withdrawn by regulatory authorities and our, or such collaborators', ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our business, operating results, financial condition and prospects.

If we fail to comply with applicable regulatory requirements following approval of any product candidates we may develop, a regulatory agency may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending BLA or supplements to a BLA submitted by us;
- seize product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any product candidates we may develop and generate revenues.

Any product candidate we may develop for which we obtain marketing approval will be subject to restrictions, such as the laws and regulations prohibiting the promotion of off-label uses, or may need to be withdrawn from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our medicines, when and if any of them are approved.

The FDA and other regulatory agencies closely regulate the post-approval marketing and promotion of medicines to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other regulatory agencies impose stringent restrictions on manufacturers' communications regarding off-label use. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we do not market our medicines for their approved indications, we may be subject to enforcement action for off-label marketing by the FDA and other federal and state enforcement agencies, including the Department of Justice, or DOJ. Violation of the Federal Food, Product, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may also lead to investigations or allegations of violations of federal and state healthcare fraud and abuse laws and state consumer protection laws. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific communications concerning their products in certain circumstances. For example, in January 2025, the FDA published final guidance outlining the agency's non-binding policies governing the distribution of scientific information on unapproved uses to healthcare providers. This final guidance calls for such communications to be truthful, non-misleading, factual, and unbiased and include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use. If a company engages in such communications consistent with the guidance's recommendations, the FDA indicated that it will not treat such communications as evidence of unlawful promotion of a new intended use for the approved product.

In addition, under some recent guidance from the FDA and the Pre-Approval Information Exchange Act, signed into law as part of the Consolidated Appropriations Act of 2023, companies may also promote information that is consistent with the prescribing information and proactively speak to formulary committee members of payors regarding data for an unapproved drug or unapproved uses of an approved drug. We may engage in these discussions and communicate with healthcare providers, payors and other constituencies in compliance with all applicable laws, regulatory guidance and industry best practices. We will need to carefully navigate the FDA's various regulations, guidance and policies, along with recently enacted legislation, to ensure compliance with restrictions governing promotion of our products.

Further, on September 9, 2025, the President issued a Memorandum directing the Department of Health and Human Services, or HHS, to "ensure transparency and accuracy in direct-to-consumer prescription drug advertising, including by increasing the amount of information regarding any risks associated with the use of any such prescription drug required to be provided in prescription drug advertisements." The same day, the FDA declared that it will no longer tolerate what it characterized as "deceptive practices" in prescription drug advertising and that the agency would "aggressively deploy" its available enforcement tools, with "heightened scrutiny" of fair balance and disclosures in social media promotions. The FDA issued a generic "notice letter" to a substantial number of companies directing such companies to "remove any noncompliant advertising and bring all promotional communications into compliance." When and if our products are approved, we will need to maintain a robust compliance program and processes designed to ensure that all such advertising activities are performed in a legal and compliant manner.

In addition, later discovery of previously unknown problems with our medicines, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such medicines, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a medicine;
- restrictions on the distribution or use of a medicine;
- requirements to conduct post-marketing clinical trials;
- receipt of warning or untitled letters;
- withdrawal of the medicines from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of medicines;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- suspension of any ongoing clinical trials;
- refusal to permit the import or export of our medicines;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any product candidates we develop and adversely affect our business, financial condition, results of operations and prospects.

Additionally, if any product candidates we may develop receive marketing approval, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy to ensure that the benefits outweigh its risks, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients and a communication plan to healthcare practitioners. Furthermore, if we or others later identify undesirable side effects caused by our product candidate, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings on the label;
- we may be required to change the way a product candidate is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

We and our contract manufacturers are subject to significant regulation. The manufacturing facilities on which we rely may not continue to meet regulatory requirements, which could materially harm our business.

All entities involved in the preparation of product candidates for clinical trials or commercial sale, including any contract manufacturers, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants or to inadvertent changes in the

properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturer must supply all necessary documentation in support of a BLA on a timely basis and must adhere to the FDA's cGLP and cGMP regulations enforced through its facilities inspection program. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of any product candidates we may develop or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, FDA approval of the products will not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. The PREVENT Pandemics Act, which was enacted in December 2022, clarifies that foreign drug manufacturing establishments are subject to registration and listing requirements even if a drug or biologic undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment outside the United States prior to being imported or offered for import into the United States.

If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new product, or revocation of a pre-existing approval. Any such consequence would severely harm our business, financial condition and results of operations.

Our relationships with healthcare providers, physicians and third-party payers will be subject to applicable anti-kickback, fraud and abuse, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payers play a primary role in the recommendation and prescription of any product candidates that we develop for which we obtain marketing approval. Our future arrangements with third-party payers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our medicines for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the federal False Claims Act, and civil monetary penalty laws which can be enforced through civil whistleblower or qui tam actions, imposes civil and criminal penalties against individuals or entities for knowingly presenting or causing to be presented, to the federal government, claims for payment or approval from Medicare, Medicaid or other government payers that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as further amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, which imposes certain requirements, including mandatory contractual terms, on covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, as well as their respective business associates and their subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security, and transmission of such individually identifiable health information;
- the federal transparency requirements under the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report to the HHS information related to payments and other transfers of value to physicians, as defined by such law, other healthcare providers and teaching hospitals and ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payers, including private insurers, and certain state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to drug pricing and payments to physicians and other healthcare providers or marketing expenditures and state and local laws that require the registration of sales representatives.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of EU Member States and the United Kingdom, such as the UK Bribery Act 2010. Violation of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are

found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Liabilities they incur pursuant to these laws could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Legislative and regulatory changes may increase the difficulty and cost for us and any future collaborators to obtain reimbursement for our product candidates, if and when approved.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of any product candidates we may develop, restrict or regulate post-approval activities and affect our ability, or the ability of any future collaborators, to profitably sell any products for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any future collaborators, may receive for any approved products.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payers.

The ACA, which became law in 2010, contains provisions of importance to our business. Our ability to commercialize and the prices we may obtain for any product candidates we may develop and that are approved for sale, may be affected by these provisions, including without limitation, the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of federal healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been adopted since the ACA was enacted. These changes include the Budget Control Act of 2011, which, among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which will remain in effect through 2031. However, as a result of other legislation, the actual reductions in Medicare payments may vary up to 4%. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Since enactment of the ACA, there have been, and continue to be, numerous executive and legal challenges and U.S. congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Act, the U.S. Congress effectively repealed the "individual mandate" by reducing the applicable penalty to zero dollars. The modification of this provision, which required most Americans to carry a minimal level of health insurance, became effective in 2019. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our potential products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers.

The prices of prescription pharmaceuticals in the United States and foreign jurisdictions are subject to considerable legislative and executive actions and could impact the prices we obtain for our products, if and when approved.

The prices of prescription pharmaceuticals have been the subject of considerable discussion in the United States. There have been several recent U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid.

In addition, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program to import certain prescription drugs from Canada into the United States. That regulation was challenged in a lawsuit by the Pharmaceutical Research and Manufacturers of America, or PhRMA, but the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. A number of states have submitted Section 804 Importation Program proposals to the FDA with the goal of obtaining authority to import drugs from Canada, subject to conditions. On May 21, 2025, the FDA announced that it would offer individual states the opportunity to submit a draft proposal for pre-review and meet with the FDA to obtain initial feedback from the FDA prior to formally submitting their Section 804 importation program proposal. The intent of these meetings is to assist states in developing their proposals by further clarifying requirements, enhancing the quality of proposals submitted to the FDA and ultimately shortening the review timeline.

On August 16, 2022, the Inflation Reduction Act, or the IRA, was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, the U.S. Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years, but it did not originally apply to drugs and biologics that have been approved for a single rare disease or condition. With passage of the OBBBA, on July 3, 2025, which was signed into law on July 4, 2025, Congress extended this exemption to drugs and biologics with multiple orphan drug designations.

Nonetheless, since CMS may establish a maximum price for these products in price negotiations, we would be fully at risk of government action if our products are the subject of Medicare price negotiations. Moreover, given the risk that could be the case, these provisions of the IRA may also further heighten the risk that we would not be able to achieve the expected return on our drug products or full value of our patents protecting our products if prices are set after such products have been on the market for nine years.

Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated “maximum fair price” under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates if they raise prices for certain Part B and Part D drugs faster than the rate of inflation. The new law also caps Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at $2,000 a year. In addition, the IRA potentially raises legal risks with respect to individuals participating in a Medicare Part D prescription drug plan who may experience a gap in coverage if they required coverage above their initial annual coverage limit before they reached the higher threshold, or “catastrophic period” of the plan. Individuals requiring services exceeding the initial annual coverage limit and below the catastrophic period must pay 100% of the cost of their prescriptions until they reach the catastrophic period. Among other things, the IRA contains many provisions aimed at reducing this financial burden on individuals by reducing the co-insurance and co-payment costs, expanding eligibility for lower income subsidy plans, and price caps on annual out-of-pocket expenses, each of which could have potential pricing and reporting implications.

The first cycle of negotiations for the Medicare Drug Price Negotiation Program commenced in the summer of 2023 with the negotiated prices for ten selected drug products becoming effective on January 1, 2026. The second cycle of negotiations with participating drug companies occurred during 2025, and the negotiated prices for this second set of fifteen drugs will become effective on January 1, 2027. On January 27, 2026, CMS published the list of fifteen drugs selected for the third cycle of negotiations. These negotiated prices will become effective on January 1, 2028.

On June 6, 2023, Merck & Co., Inc., filed a lawsuit against HHS and CMS asserting that, among other things, the IRA’s Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the U.S. Constitution. Subsequently, other parties, including the U.S. Chamber of Commerce, or Chamber of Commerce, Bristol Myers Squibb Company, the PhRMA, Astellas Pharma US, Inc., Novo Nordisk Inc., Janssen Pharmaceuticals, Inc., Novartis Pharmaceutical Corporation, AstraZeneca L.P. and Boehringer Ingelheim Pharmaceuticals, Inc. also filed lawsuits in various courts with similar constitutional claims against HHS and CMS. HHS has generally won the substantive disputes in these cases or succeeded in getting claims dismissed for lack of standing or on the merits. We expect that litigation involving these provisions of the IRA will continue, with unpredictable and uncertain results. Accordingly, we cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, if approved, any of which could adversely affect our business, results of operations and financial condition.

Since adoption of the IRA, the Trump Administration has taken a number of actions to reduce the costs of pharmaceutical products. For example, on April 15, 2025, President Trump issued an Executive Order

which directs HHS to take steps to reduce the prices of pharmaceutical products. Further, on May 12, 2025, President Trump issued an additional Executive Order calling on pharmaceutical manufacturers to voluntarily reduce the prices of medicines in the United States. The Order provides that if such actions do not lower the costs of pharmaceuticals, the Secretary of HHS would pursue other actions, including proposing a rulemaking that imposes most favored nation, or MFN, pricing in the United States. Thereafter, on July 31, 2025, the President issued letters to 17 pharmaceutical companies reiterating the requirements of the May 12, 2025 Executive Order and demanding that such companies extend MFN pricing to Medicaid patients. Virtually all of these pharmaceutical companies have entered into agreements with the administration to provide for lower prices on certain pharmaceuticals.

On December 23, 2025, CMS, through its Center for Medicare and Medicaid Innovation, proposed two five-year pilot programs to implement a “reference pricing” regime for drugs paid for under Medicare for 25% of covered beneficiaries. The programs are referred to as the Global Benchmark for Efficient Drug Pricing Model for Medicare Part B drugs and the Guarding U.S. Medicare Against Rising Drug Costs for Medicare Part D drugs. Under the proposed pilot programs, a manufacturer would owe rebates to Medicare if prices for their drugs exceeded the prices paid by other economically comparable reference countries, defined in the proposed regulations as the Organization for Economic Co-operation and Development countries with a gross domestic product, or GDP, of $400 billion and a per capita GDP that is at least 60% of the U.S. per capita GDP (an initial list of 19 reference countries is included in the proposed rule). The pilot programs are proposed to go into effect beginning October 1, 2026.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for any product candidates we may develop or additional pricing pressures.

In addition, in some countries including those member states of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices, and in certain instances render commercialization in certain markets infeasible or disadvantageous from a financial perspective. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product and/or our product candidates to other available products in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third party payors or government authorities may lead to further pressure on the prices or reimbursement levels. If reimbursement of our products, if any, is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, the commercial launch of our product candidates may be delayed, possibly for lengthy periods of time, we or our collaborators may not launch at all in a particular country, we may not be able to recoup our investment in one or more product candidates, and there could be a material adverse effect on our business.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies,

managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for product candidates that we may identify, if we obtain regulatory approval;
- our ability to receive or set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies, and contractual obligations and failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition, results of operations or prospects.

We are subject to data privacy and protection laws, regulations, policies and contractual obligations that apply to the collection, transmission, storage and use of personally-identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information, including comprehensive regulatory systems in the United States, European Union and United Kingdom. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. These obligations may be applicable to some or all of our business activities now or in the future.

If we are unable to properly protect the privacy and security of protected health information, we could be found to have violated these privacy and security laws and/or breached certain contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face significant civil and criminal penalties. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

In addition to potential enforcement by HHS, we are also potentially subject to privacy enforcement from the Federal Trade Commission, or the FTC. The FTC has been particularly focused on the unpermitted processing of health and genetic data through its recent enforcement actions and is expanding the types of privacy violations that it interprets to be “unfair” under Section 5 of the Federal Trade Commission Act, as well as the types of activities it views to trigger the Health Breach Notification Rule, which the FTC also has the authority to enforce. The FTC is also in the process of developing rules related to commercial surveillance and data security that may impact our business. We will need to account for the FTC’s

evolving rules and guidance for proper privacy and data security practices in order to mitigate our risk for a potential enforcement action, which may be costly. If we are subject to a potential FTC enforcement action, we may be subject to a settlement order that requires us to adhere to very specific privacy and data security practices, which may impact our business. We may also be required to pay fines as part of a settlement, depending on the nature of the alleged violations. If we violate any consent order that we reach with the FTC, we may be subject to additional fines and compliance requirements.

There are also increased restrictions at the federal level relating to transferring sensitive data outside of the United States to certain foreign countries. For example, in 2024, Congress passed H.B. 815, which included the Protecting Americans' Data from Foreign Adversaries Act of 2024. This law creates certain restrictions for entities that disclose sensitive data (including potential health data) to countries such as China. Failure to comply with these rules can lead to a potential FTC enforcement action. Additionally, the DOJ recently finalized a rule implementing Executive Order 14117, which implements the DOJ's Data Security Program, or DSP, and creates similar restrictions related to the transfer of sensitive U.S. data to countries such as China. Violations of the DSP can lead to both civil and criminal penalties, and it is unclear how aggressively the DOJ will enforce the new program. These data transfer restrictions (and others that may pass in the future) may create operational challenges and legal risks for our business.

States are also active in creating specific rules relating to the processing of personal information. In 2018, California passed into law the California Consumer Privacy Act, or the CCPA, which took effect on January 1, 2020 and imposed many requirements on businesses that process the personal information of California residents. Many of the CCPA's requirements are similar to those found in the General Data Protection Regulation, or the GDPR, which is further described below, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of the sale of their personal information. The CCPA contains significant penalties for companies that violate its requirements. In November 2020, California voters passed a ballot initiative for the California Privacy Rights Act, or the CPRA, which went into effect on January 1, 2023 and significantly expanded the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also created a new enforcement agency – the California Privacy Protection Agency – whose sole responsibility is to enforce the CPRA and other California privacy laws, which will further increase compliance risk. The provisions in the CPRA may apply to some of our business activities.

In addition to California, a number of other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect over the next few years. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of "sensitive" data, which includes health data in some cases. For example, the State of Washington passed the My Health My Data Act in 2023 which specifically regulated health information that is not otherwise regulated by the HIPAA rules, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data, and more states are considering such legislation. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Similar to the laws in the United States, there are significant privacy and data security laws that apply in Europe and other countries. The collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the European Economic Area, or the EEA, and the processing of personal data that takes place in the EEA, is regulated by the GDPR, which went into effect in May 2018 and which imposes obligations on companies that operate in

our industry with respect to the processing of personal data and the cross-border transfer of such data. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. If our or our service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to 20 million Euros or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill.

The GDPR places restrictions on the cross-border transfer of personal data from the European Union to countries that have not been found by the European Union to offer adequate data protection legislation, such as the United States. There are ongoing concerns about the ability of companies to transfer personal data from the European Union to other countries. In July 2020, the Court of Justice of the European Union, or the CJEU, invalidated the EU-U.S. Privacy Shield, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the United States. The CJEU decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA to the United States.

Following the July 2020 Court of Justice of the European Union judgment invalidating the so-called EU-U.S. Privacy Shield, the European Commission adopted an adequacy decision for the EU-U.S. Data Privacy Framework in July 2023. This adequacy decision permits U.S. companies who self-certify under the EU-U.S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the European Union to the United States. However, some privacy advocacy groups have already suggested that they will be challenging the EU-U.S. Data Privacy Framework, and there is currently one pending litigation against the EU-U.S. Data Privacy Framework before the CJEU, C-703/25 P – *Latombe v Commission*. If these challenges are successful, they may not only impact the EU-U.S. Data Privacy Framework, but also further limit the viability of the so-called standard contractual clauses and other data transfer mechanisms.

Additionally, in October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which serves as a replacement to the EU-U.S. Privacy Shield. The European Union initiated the process to adopt an adequacy decision for the EU-U.S. Data Privacy Framework in December 2022, and the European Commission adopted the adequacy decision on July 10, 2023. The adequacy decision permits U.S. companies who self-certify to the EU-U.S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the European Union to the United States. However, some privacy advocacy groups have already suggested that they will be challenging the EU-U.S. Data Privacy Framework. If these challenges are successful, they may not only impact the EU-U.S. Data Privacy Framework, but also further limit the viability of the standard contractual clauses and other data transfer mechanisms. The uncertainty around this issue has the potential to impact our business.

Following the withdrawal of the United Kingdom from the European Union, the UK Data Protection Act 2018 applies to the processing of personal data that takes place in the United Kingdom and includes parallel obligations to those set forth by GDPR. In relation to data transfers, both the United Kingdom and the European Union have determined, through separate "adequacy" decisions, that data transfers between the two jurisdictions are in compliance with the UK Data Protection Act and the GDPR, respectively. The United Kingdom and the United States have also agreed to a to develop a U.S.-UK "Data Bridge", which functions similarly to the EU-U.S. Data Privacy Framework and provides an additional legal mechanism for companies to transfer data from the UK to the United States. In addition to the UK, Switzerland is also in the process of approving an adequacy decision in relation to the Swiss-U.S. Data Privacy Framework (which would function similarly to the EU-U.S. Data Privacy Framework and the U.S.-UK Data Bridge in relation to data transfers from Switzerland to the United States). Any changes or updates to these developments have the potential to impact our business.

Beyond GDPR and similar laws in the United States, there are privacy and data security laws in a growing number of countries around the world. While many loosely follow GDPR as a model, other laws contain different or conflicting provisions. These laws may impact our ability to conduct our business activities.

While we continue to address the implications of the recent changes to data privacy regulations, data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges, and our efforts to comply with the evolving data protection rules may be unsuccessful. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices, which could adversely affect our business. We must devote significant resources to understanding and complying with this changing landscape. Failure to comply with federal, state and international laws regarding privacy and security of personal information could expose us to fines and penalties under such laws. Any such failure to comply with data protection and privacy laws could result in government-imposed fines, penalties or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement actions, litigation and significant costs for remediation, reputational harm, diminished profits and earnings, additional reporting requirements and/or oversight, any of which could adversely affect our business, our results of operations or prospects. We also face a threat of consumer class actions related to these laws and the overall protection of personal data. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business, financial condition, results of operations or prospects.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, consultants, partners and the principal investigators in our clinical trials. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the European Union and other jurisdictions, provide accurate information to the FDA, the European Commission and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

Laws and regulations governing any international operations we may have may preclude us from developing, manufacturing and selling certain product candidates outside of the United States or adversely impact our ability to operate our business outside the United States. In addition, changes in and uncertainty surrounding U.S. trade policy could have a material adverse impact on our business, financial condition and results of operations.

We are subject to numerous laws and regulations in each jurisdiction outside the United States in which we operate. The creation, implementation and maintenance of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing the provision of money or anything of value, directly or indirectly through third parties, to any foreign official, official of a public international organization, or political party official or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the DOJ. The SEC is involved with enforcement of the books and records provisions of the FCPA.

Compliance with the FCPA and other anti-corruption laws potentially applicable to our business is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, compliance with the FCPA and other anti-corruption laws presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials.

Various U.S. export and sanctions laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of certain products and technical data relating to those products. Furthermore, such export and sanctions laws include restrictions or prohibitions on the sale or supply of certain products and services to United States embargoed countries or sanctioned countries, governments, persons and entities. Our operations outside of the United States have required, and will continue to require, us to dedicate additional resources to comply with laws governing international business practices, and these laws may preclude us from developing, manufacturing or selling certain drugs and drug candidates outside of the United States, which could limit our growth potential and increase our development costs. The failure to comply with these laws may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA and export and sanctions laws can result in significant civil and criminal penalties, imprisonment, the loss of export or import privileges, debarment, breach of contract and fraud litigation, reputational harm, and other consequences. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Changes in and uncertainty surrounding United States trade policy could have a material adverse impact on our business, financial condition and results of operations.

The Trump administration, in 2025, initiated a series of tariff-related actions against U.S. trading partners. On April 2, 2025, President Trump issued an executive order announcing a "baseline" reciprocal tariff of 10% on all U.S. trading partners effective April 5, 2025, and higher individualized reciprocal tariffs on 57 countries (with certain product exemptions for pharmaceutical-related products, among others). Previously, the administration had imposed a 25% tariff on Canada and Mexico for goods not covered by the United States-Mexico-Canada Agreement, or USMCA, and tariffs equaling 20% on China. In response, several countries threatened retaliatory measures, including Canada and China, which then imposed retaliatory tariffs. Prior to when the country-specific reciprocal tariffs were scheduled to take effect, the administration delayed the effective date of such tariffs for all countries except China to August 1, 2025. Several countries have reached deals with the United States that include reduced tariff rates to varying levels and other measures, including the United Kingdom, Vietnam, Indonesia, Japan, the Philippines, South Korea, Thailand, Malaysia, Cambodia, China, El Salvador, Argentina, Ecuador, Guatemala, Switzerland, Liechtenstein, Taiwan and countries in the European Union.

The United States and China reached a framework agreement that resulted in the suspension of the higher reciprocal tariffs on China, and the two countries later conducted high-level talks in November 2025 that resulted in a framework deal holding tariffs at 20%. Sustained uncertainty about, or the further escalation of, trade and political tensions between the United States and China could result in a disadvantageous research and manufacturing environment in China, particularly for U.S. based companies, including retaliatory restrictions that hinder or potentially inhibit our ability to rely on contract development and manufacturing organizations and other service providers that operate in China.

Regarding Canada and Mexico, as of October 31, 2025, the rate remained 25% for goods that are not covered by the USMCA for Mexico and, effective August 1, 2025, was increased to 35% on imports from Canada that are not covered by the USMCA. Certain other countries, including Japan, South Korea and the United Kingdom, as well as the European Union, have reached agreements with the United States that cap pharmaceutical tariffs at 15%.

Separately, in April 2025, the U.S. Department of Commerce initiated an investigation under Section 232 of the Trade Expansion Act of 1962 into the impact on U.S. national security of the imports of pharmaceuticals and pharmaceutical ingredients, including finished drug products, medical countermeasures, critical inputs such as active pharmaceutical ingredients, and key starting materials, and derivative products of those items. On September 25, 2025, via a post on Truth Social, President Trump announced that, beginning October 1, 2025, all branded or patented drugs imported in the United States would face a 100% tariff. At the same time, Trump indicated that these tariffs could be avoided by building pharmaceutical manufacturing facilities in the United States. Thereafter, Trump delayed the October 1, 2025 effective date of the tariffs, announcing that the Administration had now "begun preparing" tariffs on manufacturers that do not build in the United States or enter into a MFN drug pricing agreement with the Trump administration.

As a result of changes in tariffs that have been announced and/or implemented, and the underlying uncertainty currently surrounding international trade, we could experience a negative impact on our costs of materials and production processes, and supply chain disruptions and delays as a result of any new tariff policies or trade restrictions. If we are unable to obtain necessary raw materials or product components in sufficient quantity and in a timely manner due to disruptions in the global supply chain caused by macroeconomic events and conditions, the development, testing and clinical trials of our product candidates may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. We cannot yet predict the effect of the recently imposed U.S. tariffs on imports, or the extent to which other countries will impose quotas, duties, tariffs, taxes or other similar restrictions upon imports or exports in the future, nor can we predict future trade policy or the terms of any renegotiated trade agreements and their impact on our business.

If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur significant costs.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health, and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research and product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws, regulations and permitting requirements. These current or future laws, regulations and permitting requirements may impair our research, development or production efforts. Failure to comply with these laws, regulations and permitting requirements also may result in substantial fines, penalties or other sanctions or business disruption. Any third-party contract manufacturers and suppliers we engage will also be subject to these and other environmental, health and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or an interruption in operations, which could in turn have a material adverse effect on our business, financial condition, results of operations and prospects.

Disruptions at the FDA and other government agencies from funding cuts, personnel losses, regulatory reforms, government shutdowns and other developments could hinder our ability to obtain guidance from the FDA regarding our clinical development programs and develop and secure approval of our product candidates in a timely manner, which would negatively impact our business.

The FDA and comparable regulatory agencies in foreign jurisdictions, such as the EMA and CHMP, play an important role in the development of our product candidates by providing guidance on our clinical development programs and reviewing our regulatory submissions, including INDs, requests for special designations and marketing applications. If these oversight and review activities are disrupted, then correspondingly our ability to develop and secure timely approval of our product candidates could be impacted in a negative manner.

For example, the recent loss and retirement of FDA leadership and personnel could lead to disruptions and delays in FDA guidance, review and approval of our product candidates. Pursuant to President Trump's executive order 14210, "Implementing the President's 'Department of Government Efficiency' Workforce Optimization Initiative," the Secretary of HHS announced on March 27, 2025, a reorganization and Reduction in Force, or RIF, across HHS of approximately 20,000 employees (82,000 to 62,000), with the FDA's workforce of approximately 20,000 to decrease by 3,500 full-time employees. Subsequently, the FDA indicated that roughly a quarter of those employees who received RIF notices had been reinstated. On July 14, 2025, following litigation reaching the U.S. Supreme Court, the administration began to carry out these layoffs across HHS, including the FDA. In November 2025, a Congressional Continuing Resolution ended the government shutdown, providing full-year funding for the FDA for the 2026 fiscal year through September 30, 2026 at approximately $7 billion with a slight increase in user fees for drug and device companies.

While the FDA's review of marketing applications and other activities for new drugs and biologics is largely funded through the user fee program established under the Prescription Drug User Free Act, or PDUFA, it remains unclear how the administration's RIF and budget cuts will impact this program and the ability of the FDA to provide guidance and review our product candidates in a timely manner. For example, while the FDA's RIF did not reportedly specifically target FDA reviewers, many operations, administrative and policy staff that help support such reviews were affected and those losses could lead to delays in PDUFA reviews and related activities. There has been at least one report in which the FDA

failed to meet a PDUFA goal date for approval of an NDA due to heavy workload and limited resources. In addition, while currently unclear, there is a risk that the RIF and budget cutbacks could threaten the integrity of the PDUFA program itself. That is because, for the FDA to obligate user fees collected under PDUFA in the first place, a certain amount of non-user fee appropriations must be spent on the process for the review of applications plus certain other costs during the same fiscal year.

There is also substantial uncertainty as to how regulatory reform measures being implemented by the Trump administration across the government will impact the FDA and other federal agencies with jurisdiction over our activities. For example, since taking office, President Trump has issued a number of executive orders that could have a significant impact on the manner in which the FDA conducts its operations and engages in regulatory and oversight activities. These include executive order 14192, “Unleashing Prosperity Through Deregulation,” January 31, 2025; executive order 14212, “Establishing the President’s Make America Healthy Again Commission,” February 13, 2025; and executive order 14219, Ensuring Lawful Governance and Implementing the President’s ‘Department of Government Efficiency' Deregulatory Initiative,” February 21, 2025. If these or other orders or executive actions impose constraints on the FDA’s ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Similarly, actions by the U.S. government have significantly disrupted the operations of U.S. government agencies such as the National Institutes of Health, National Science Foundation, Centers for Disease Control and Prevention, and the FDA, which have traditionally provided funding for basic research, research and development, and clinical testing. These U.S. government actions have included, among other things, suspending, terminating and withholding of disbursements of funds owed under ongoing contracts, grants, and other financial assistance agreements; declining to continue multi-year research projects for additional annual budget periods; canceling or delaying solicitations for new contract, grant and other financial assistance awards; canceling or delaying proposal evaluation processes and issuance of such new awards; substantially reducing federal agency staff responsible for managing contract and financial assistance programs; eliminating agency information and resources for facilitating research activity; delaying or terminating federal agency procedures for authorizing international transactions; initiating aggressive enforcement actions that may disrupt the operations of major research universities that are significant contributors to life sciences research in the United States, and threatening access to federal agency contracts and other funding awards based on companies’ otherwise lawful corporate policies and choice of counsel. These U.S. government actions could, directly or indirectly, significantly disrupt, delay, prevent, or increase the costs of our research and product commercialization programs, including our ability to develop new product candidates, conduct clinical trials, implement research collaborations with other companies or institutions, and obtain approvals to market and sell new products.

In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions and could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

For example, the federal government shut down on October 1, 2025. With the shutdown, the FDA issued a public notice stating that agency operations would continue to the extent permitted by law, such as activities necessary to address imminent threats to the safety of human life and activities funded by carryover user fee funds. At the same time, the FDA declared that, during the shutdown period, it does not have legal authority to accept user fees assessed for fiscal year 2026 until an appropriation or continuing resolution for the FDA is enacted for such fiscal year. As a result, the FDA will not be able to accept any regulatory submissions for fiscal year 2026 that require a fee payment and that are submitted during the lapse period.

At the same time, disruptions at the FDA and other government agencies may result from public health events similar to the COVID-19 pandemic. For example, during the pandemic, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. In the event of a similar public health emergency in the future, the FDA may not be able to continue its current pace and review timelines could be extended. Regulatory authorities outside the United States facing similar circumstances may adopt similar restrictions or other policy measures in response to a similar public health emergency and may also experience delays in their regulatory activities.

Accordingly, if any of the foregoing developments or others impact the ability of the FDA to provide us with guidance regarding our clinical development programs or delay the FDA's review and processing of our regulatory submissions, including INDs and BLAs, our business would be negatively impacted. Further, any future government shutdown could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks related to employee matters, managing growth and other operational matters

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the research and development, clinical, financial, operational and other business expertise of our executive officers, as well as the other principal members of our management, scientific and clinical teams. Although we have entered into employment offer letters with our executive officers, each of them may terminate their employment with us at any time. For example, in 2025, we had several changes in our executive management team. We do not maintain "key person" insurance for any of our executives or other employees. Recruiting and retaining qualified scientific, clinical, manufacturing, accounting, legal and sales and marketing personnel will also be critical to our success.

The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Our success as a public company also depends on implementing and maintaining internal controls and the accuracy and timeliness of our financial reporting. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of February 27, 2026, we had 258 full-time employees. As our development progresses, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, clinical, regulatory affairs and, if any product candidate we may develop receives marketing approval, sales, marketing, distribution and coverage and reimbursement capabilities. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to

effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

As a growing biotechnology company, we are actively pursuing new platforms and product candidates in many therapeutic areas and across a wide range of diseases. Successfully developing product candidates for, and fully understanding the regulatory and manufacturing pathways to, all of these therapeutic areas and disease states requires a significant depth of talent, resources and corporate processes in order to allow simultaneous execution across multiple areas. Due to our limited resources, we may not be able to effectively manage this simultaneous execution and the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, operational mistakes, legal or regulatory compliance failures, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to compete effectively and commercialize our product candidates, if approved, will depend in part on our ability to effectively manage the future development and expansion of our company.

Future acquisitions or strategic alliances could disrupt our business and harm our financial condition and results of operations.

We may acquire businesses, technologies or assets, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products or product candidates resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction. The risks we face in connection with acquisitions, include:

- diversion of management time and focus from operating our business to addressing acquisition integration challenges;
- coordination of research and development efforts;
- retention of key employees from the acquired company;
- changes in relationships with collaborators as a result of product acquisitions or strategic positioning resulting from the acquisition;
- cultural challenges associated with integrating employees from the acquired company into our organization;
- the need to implement or improve controls, procedures and policies at a business that prior to the acquisition may have lacked sufficiently effective controls, procedures and policies;
- liability for activities of the acquired company before the acquisition, including intellectual property infringement claims, violation of laws, commercial disputes, tax liabilities and other known liabilities;
- unanticipated write-offs or charges; and
- litigation or other claims in connection with the acquired company, including claims from terminated employees, customers, former stockholders or other third parties.

Our failure to address these risks or other problems encountered in connection with any future acquisitions or strategic alliances could cause us to fail to realize the anticipated benefits of these transactions, cause us to incur unanticipated liabilities and harm the business generally. There is also a risk that future acquisitions will result in the incurrence of debt, contingent liabilities, amortization expenses or incremental operating expenses, any of which could harm our financial condition or results of operations.

Our internal information technology systems, or those of our vendors, collaborators or other contractors or consultants, may fail or suffer security breaches, loss or leakage of data and other disruptions or compromise, which could result in a material disruption of our product development programs, compromise sensitive information related to our business or prevent us from accessing critical information, trigger contractual and legal obligations, potentially exposing us to liability, reputational harm or otherwise adversely affecting our business and financial results.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including, but not limited to, intellectual property, proprietary business information and personal information). It is critical that we, and our vendors, collaborators or other contractors or consultants, do so in a secure manner to maintain the availability, security, confidentiality, privacy and integrity of such confidential information.

Despite the implementation of security measures, given the size and complexity of our internal information technology systems and those of our current and any future vendors, collaborators and other contractors and consultants, and the increasing amounts of confidential information that they maintain, such information technology systems are vulnerable to damage or interruption from computer viruses, computer hackers, malicious code, employee error, theft or misuse, denial-of-service attacks, sophisticated nation-state and nation-state-supported actors, unauthorized access, natural disasters, terrorism, war, telecommunication and electrical failures or other compromise. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies.

Although we seek to protect our information technology systems from system failure, accident and security breach, our efforts may not be successful. If such an event were to occur, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary or confidential information or other disruptions. For example, the loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If we were to experience a significant cybersecurity breach of our information systems or data, the costs associated with the investigation, remediation and potential notification of the breach to counterparties, data subjects, regulators or others could be material. In addition, our remediation efforts may not be successful. Moreover, if the information technology systems of our vendors, collaborators and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, we could suffer significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary information.

To the extent that any disruption or security breach were to result in a loss of, or damage to, our or our vendors', collaborators' or other contractors' or consultants' data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability including litigation exposure, penalties and fines, we could become the subject of regulatory action or investigation, our competitive position and reputation could be harmed and the further development and commercialization of our product candidates could be delayed. As a result of such an event, we may be in breach of our contractual obligations. Furthermore, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our customers or employees, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damage. Any of the above could have a material adverse effect on our business, financial condition, results of operations or prospects.

The financial exposure from the events referenced above could either not be insured against or not be fully covered through any insurance that we maintain and could have a material adverse effect on our business, financial condition, results of operations or prospects. In addition, we cannot be sure that our existing insurance coverage will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages as a result of the events referenced above.

Our operations or those of the third parties upon whom we depend might be affected by the occurrence of a natural disaster, pandemic or other catastrophic event.

We depend on our employees, consultants, CMOs and CROs, as well as regulatory agencies and other parties, for the continued operation of our business. Although we maintain disaster recovery plans, they might not adequately protect us. Despite any precautions we take for natural disasters or other catastrophic events, these events, including terrorist attack, pandemics, hurricanes, fire, floods and ice and snowstorms, could result in significant disruptions to our research and development, preclinical studies, clinical trials, and, ultimately, commercialization of our products. Long-term disruptions in the infrastructure caused by events, such as natural disasters, the outbreak of war, the escalation of hostilities and acts of terrorism or other ‘‘acts of God,’’ particularly involving cities in which we have offices, manufacturing or clinical trial sites, could adversely affect our businesses. Although we carry business interruption insurance policies and typically have provisions in our contracts that protect us in certain events, our coverage might not respond or be adequate to compensate us for all losses that may occur. Any natural disaster or catastrophic event affecting us, our CMOs or CROs, regulatory agencies or other parties with which we are engaged could have a significant negative impact on our operations and financial performance.

Risks related to ownership of our common stock and our status as a public company

The price of our common stock is volatile and fluctuates substantially, which could result in substantial losses for our stockholders.

Our stock price has been, and is likely to continue to be, volatile. The stock market in general, and the market for smaller biopharmaceutical companies in particular, have experienced extreme price volatility and volume fluctuations that have often been unrelated to the operating performance of particular companies. As a result of this volatility, our stockholders may not be able to sell their common stock at or above the price they paid for their shares. The market price for our common stock may be influenced by many factors, including:

- timing and results of, or developments in, preclinical studies and clinical trials of any product candidates we may develop or those of our competitors or potential collaborators;
- adverse regulatory decisions, including failure to receive clearance to initiate clinical trials or obtain marketing approvals for any product candidates we may develop;
- our success in commercializing any product candidates that may be approved;

- the success of competitive products or technologies;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other intellectual property or proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any product candidates we may develop;
- the results of our efforts to discover, develop, acquire or in-license products, product candidates, technologies or data referencing rights, the costs of commercializing any such products and the costs of development of any such product candidates or technologies;
- actual or anticipated changes in estimates as to our financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or the financial results of companies that are perceived to be similar to us;
- sales of our common stock by us, our executive officers, directors or principal stockholders or others;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry, political and market conditions; and
- the other factors described in this “Risk Factors” section.

In the past, following periods of volatility in the market price of a company’s securities, securities class-action litigation has often been instituted against that company. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our offerings or business practices. Such litigation may also cause us to incur other substantial costs to defend such claims and divert management’s attention and resources.

If securities analysts do not publish or cease publishing research or reports or publish misleading, inaccurate or unfavorable research about our business or if they publish negative evaluations of our stock, the price and trading volume of our stock could decline.

The trading market for our common stock relies, in part, on the research and reports that industry or financial analysts publish about us or our business. We do not have control over these analysts. There can be no assurance that existing analysts will continue to cover us or that new analysts will begin to cover us. There is also no assurance that any covering analysts will provide favorable coverage. If one or more of the analysts covering our business downgrade their evaluations of our stock or publish inaccurate or unfavorable research about our business, or provide more favorable relative recommendations about our competitors, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price and trading volume to decline.

Unfavorable global economic conditions could adversely affect our business, financial condition, stock price and results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, the 2008 global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn resulting from a pandemic, such as the COVID-19 pandemic, could result in a variety of risks to our business, including weakened demand for any product candidates we may develop. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could impair

our ability to achieve our growth strategy, could harm our financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that our current or future service providers, manufacturers or other collaborators may not survive such difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. We cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our executive officers and directors and their affiliates, if they choose to act together, have the ability to significantly influence all matters submitted to stockholders for approval.

Our executive officers and directors and their affiliates, in the aggregate, beneficially owned shares representing approximately 9.8% of our common stock as of February 27, 2026. As a result, if these stockholders were to choose to act together, they would be able to significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs, even though some of these persons or entities may have interests different than yours. For example, these stockholders, if they choose to act together, could significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

This concentration of ownership may:

- delay, defer or prevent a merger, consolidation or sale of all or substantially all of our assets that may be desired by other stockholders;
- delay, defer or prevent a change in control transaction involving us that other stockholders may desire; or
- entrench our management and board of directors.

We have broad discretion in the use of our cash, cash equivalents and marketable securities and may not use them effectively.

Our management has broad discretion in the application of our cash, cash equivalents and marketable securities and could use such funds in ways that do not improve our results of operations or enhance the value of our common stock or in ways that our stockholders may not agree with. The failure by our management to apply these funds effectively could result in financial losses that could cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest these funds in a manner that does not produce income or that loses value.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be the sole source of gain for our stockholders.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of our Loan Agreement with Hercules preclude us from paying dividends without the lender's consent or at all. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

A significant portion of our total outstanding shares may be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock or impair our ability to raise capital through the sale of equity securities in the future. As of February 27, 2026, we had 165,027,119 shares of common stock outstanding.

All of our outstanding shares of common stock are available for sale in the public market, subject to applicable securities laws.

Moreover, holders of a substantial number of shares of our common stock and shares of our common stock issuable upon exercise of outstanding options have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also filed registration statements on Form S-8 to register all of the shares of common stock that we are able to issue under our equity compensation plans. Shares registered under these registration statements on Form S-8 can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates, vesting arrangements and exercise of options.

We have incurred and will continue to incur increased costs as a result of operating as a public company, and our management has devoted and will continue to be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly as we are no longer an emerging growth company, or EGC, or a smaller reporting company, or SRC, we will incur significant legal, accounting and other expenses that we did not previously incur as a private company or as an EGC and SRC. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. As a result of no longer being able to take advantage of the exemptions from various reporting requirements that are applicable to EGCs and SRCs, we are required to comply with auditor attestation requirements, increased disclosure obligations and other reporting requirements which will likely increase our costs in the upcoming fiscal year. Our management and other personnel devote and will need to continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs, particularly as we hire additional financial and accounting employees to meet public company internal control and financial reporting requirements and will make some activities more time-consuming and costly compared to when we were a private company. For example, as a public company it is more difficult and more expensive for us to obtain director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantial costs. The impact of these events could also make it more difficult for us to attract and retain qualified members of our board of directors.

We cannot predict or estimate the amount of costs we may incur to continue to operate as a public company, nor can we predict the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404, we are required to furnish a report by our management on our internal control over financial reporting and our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting. If we have an unremediated material weakness, we would receive an adverse opinion regarding our internal control over financial reporting from our independent registered public accounting firm. We are engaged in a continuous process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, including through hiring additional financial and accounting personnel, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses in our internal control over financial reporting, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could harm our business and have a negative effect on the trading price of our stock.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. Our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation, which could have a negative effect on the trading price of our stock.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current directors and members of management.

Provisions in our restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and

- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our certificate of incorporation or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our restated certificate of incorporation designates the Court of Chancery of the State of Delaware and the federal district courts of the United States of America as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers and employees.

Our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or stockholders to our company or our stockholders;
- any action asserting a claim arising pursuant to any provision of the DGCL or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; or
- any action asserting a claim arising pursuant to any provision of our certificate of incorporation or bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine.

These choice of forum provisions will not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act of 1933, or the Securities Act, creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any claims arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees. If a court were to find either exclusive forum provision contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving such action in other jurisdictions, all of which could materially adversely affect our business, financial condition and operating results.

General Risk Factors

Changes in patent law in the United States or worldwide could diminish the value of patents in general, thereby impairing our ability to protect any product candidates we may develop and our technology.

Changes in either the patent laws or interpretation of patent laws in the United States and worldwide, including patent reform legislation such as the Leahy-Smith America Invents Act, or the Leahy-Smith Act, could increase the uncertainties and costs surrounding the prosecution of any owned or in-licensed patent applications and the maintenance, enforcement or defense of any current in-licensed issued patents and issued patents we may own or in-license in the future. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our in-licensed issued patents and issued patents we may own or in-license in the future, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Because patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim unpatentable even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to review patentability of our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. As one example, in the case Assoc. for Molecular Pathology v. Myriad Genetics, Inc., the U.S. Supreme Court held that certain claims to DNA molecules are not patentable simply because they have been isolated from surrounding material. Moreover, in 2012, the USPTO issued a guidance memo to patent examiners indicating that process claims directed to a law of nature, a natural phenomenon or a naturally occurring relation or correlation that do not include additional elements or steps that integrate the natural principle into the claimed invention such that the natural principle is practically applied and the claim amounts to significantly more than the natural principle itself should be

rejected as directed to patent-ineligible subject matter. Accordingly, in view of the guidance memo, there can be no assurance that claims in our patent rights covering any product candidates we may develop or our technology will be held by the USPTO or equivalent foreign patent offices or by courts in the United States or in foreign jurisdictions to cover patentable subject matter. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future.

Changes in tax laws or regulations or in their implementation or interpretation may adversely affect our business and financial condition.

Income, sales, use or other tax laws, statutes, rules, or regulations could be enacted or amended at any time, which could affect our business or financial condition, including causing potentially adverse impacts to our effective tax rate, tax liabilities and cash tax obligations. For example, the IRA was signed into law in August 2022, and the OBBBA was signed into law in July 2025. The IRA introduced new tax provisions, and in particular imposes a 1% excise tax on certain stock repurchases by publicly traded corporations. The OBBBA contains numerous tax provisions that we are currently in the process of evaluating, and which may significantly affect our business or financial condition. The recent changes under the OBBBA include tax rate extensions and changes to the business interest deduction limitation, the expensing of domestic research and development expenditures (in contrast to the continued capitalization and amortization of foreign research and development expenditures), the bonus depreciation deduction rules and the international tax framework. Regulatory guidance under the IRA, the OBBBA, and additional tax-related legislation is and continues to be forthcoming, and such guidance could ultimately increase or lessen the impact of these laws on our business and financial condition. In addition, it is uncertain if and to what extent various states will conform to such legislation.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Overview

We recognize the importance of identifying, assessing and managing material risks associated with cybersecurity threats. Cybersecurity considerations are integrated into our enterprise risk management framework and are designed to protect our information systems, safeguard confidential information (including employee and patient information), and support the continuity of our business operations. Our program is informed by industry-standard security and risk management practices and is designed to evolve with changes in our threat environment and regulatory requirements.

Risk Management and Strategy

We maintain processes, technologies and controls intended to prevent, detect, and respond to cybersecurity threats and to manage material risks arising from such threats. These activities include:

Risk Assessment & Monitoring

We conduct periodic cybersecurity risk assessments and maintain continuous monitoring of our environment, informed by internal processes and by third-party service providers. We engage independent cybersecurity firms to perform internal and external penetration testing. We also maintain 24x7 Network Operations Center, or NOC, and Security Operations Center, or SOC, monitoring and support services through outsourced providers.

Access to Management & Technical Controls

We utilize access controls, including multifactor authentication, to reduce risks of unauthorized access. Third-party access to our systems is provisioned using the principle of least privilege and/or role-based access, as appropriate.

Incident Response & Resilience

We maintain an incident response plan that addresses triage, severity assessment, investigation, escalation, containment, remediation, and compliance with potentially applicable legal obligations and contractual requirements. We periodically test our incident response procedures, including tabletop exercises with IT and security personnel, key internal stakeholders, and external partners. We also periodically test our disaster recovery plans to support business continuity and preparedness for disaster recovery incidents.

Third-Party & Supply Chain Risk

We assess cybersecurity risks associated with third-party service providers— including those in our supply chain and those with access to our systems or to employee or patient data—through initial due diligence and periodic reassessments based on risk tiering. We incorporate security requirements into applicable agreements and monitor certain higher-risk providers on an ongoing basis. Third-party risks are integrated into our broader risk management processes.

Policies, Training & Awareness

We conduct annual policy re-training for all employees covering data protection, breach reporting and data classification. We provide periodic cybersecurity awareness training on topics such as social engineering, phishing, password protection, confidential data handling and acceptable use. We also conduct regular simulated phishing tests to reinforce awareness and reporting.

Regulatory Monitoring

We monitor evolving cybersecurity threats and applicable data protection and privacy laws and regulations and update our processes to maintain compliance and resiliency.

Insurance

We maintain cybersecurity risk insurance intended to cover certain costs and liabilities associated with cybersecurity incidents, subject to customary retentions, limits and exclusions. Insurance coverage may not be available for all potential losses.

Governance

Board Oversight

The Audit Committee of the Board of Directors is responsible for oversight of our cybersecurity risk assessment, risk management and incident response procedures. The Audit Committee receives periodic updates from management on cybersecurity threat trends, our risk management and strategy processes, significant developments, and preparedness activities, and it provides updates to the full Board. Members

of the Board regularly engage with management on cybersecurity developments and discuss updates to our cybersecurity risk management and strategy programs.

In addition, we maintain two management-level governance bodies that provide cross-functional oversight and escalation pathways:

- An AI Governance Committee, which meets periodically to review risks associated with the development and use of artificial intelligence technologies across the company; and
- A Security and Privacy Governance Committee, a cross-functional team of leaders that meets periodically to review internal and external security and privacy risks and to coordinate controls, compliance activities and remediation priorities.

These committees inform management's reporting to the Audit Committee and facilitate timely escalation of relevant matters.

Management's Role and Expertise

Our cybersecurity risk assessment, management and strategy processes are led by our Vice President, Head of Technology, a Certified Information Security Manager with over 20 years of experience in information security, privacy, cybersecurity strategy and program implementation. The Vice President oversees prevention, mitigation, detection and remediation activities and is responsible for our incident response plan and escalation processes.

Management is supported by internal and external specialists, including a Senior Engineer for Information Security, who reports to the Vice President and holds a master's degree in cybersecurity, and by outsourced 24x7 NOC and SOC providers that deliver continuous monitoring and support. Incident severity thresholds and defined escalation criteria govern reporting to senior leadership and the Audit Committee.

Incident Response, Business Continuity and Disaster Recovery

Our incident response plan coordinates internal and third-party activities to prepare for, respond to and recover from cybersecurity incidents. These activities include identification, triage and severity assessment; investigation and containment; eradication and remediation; and post-incident lessons learned. As appropriate, we address notification and other legal or contractual obligations. We conduct tabletop exercises involving IT and security personnel, key business stakeholders and external partners to evaluate and improve our effectiveness, and we periodically test disaster recovery plans to help ensure operational resilience.

Third-Party Risk Management

We evaluate cybersecurity risks associated with third-party service providers through initial due diligence and periodic reassessments. For providers with access to sensitive data or critical systems, we require adherence to defined security standards and contractual obligations and apply least-privilege and/or role-based access controls. We perform ongoing monitoring of certain higher-risk providers and integrate third-party risks into our enterprise risk management processes.

Material Impacts from Cybersecurity Threats

Based on our assessments using the processes described above, we have not identified any cybersecurity incidents that have had a material impact on our business strategy, results of operations or financial condition. However, cybersecurity threats continue to evolve and could materially affect us in the future. Additional information about risks related to cybersecurity and privacy is included in Item 1A. Risk Factors, which should be read in conjunction with this Item 1C. We intend to comply with applicable reporting obligations regarding any material cybersecurity incidents.

Ongoing Program Evolution

We continue to evaluate and enhance our cybersecurity capabilities— including governance, controls, monitoring, training, third-party risk management and resilience measures— as the threat landscape and regulatory requirements evolve. No cybersecurity program can eliminate all risk, and there can be no assurance that our controls will prevent or mitigate all cybersecurity events or their potential impacts.

Item 2. Properties.

Our principal facilities are located at 1560 Trapelo Road, Waltham, Massachusetts, where we lease and occupy approximately 68,000 square feet of office and laboratory space. The current term of our lease expires in March 2030, with an option to extend the lease for two successive five-year terms. We believe our facilities are adequate and suitable for our current needs and that should it be needed, suitable additional or alternative space will be available to accommodate our operations.

Item 3. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock has traded on the Nasdaq Global Select Market under the symbol "DYN" since September 17, 2020. Prior to that date, there was no public trading market for our common stock.

Holders

As of February 27, 2026, we had ten holders of record of our common stock. The actual number of stockholders is greater than the number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. The number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid cash dividends on our common stock since our inception. We currently intend to retain all available funds and any future earnings to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to declare and pay dividends will be made at the discretion of our board of directors and will depend on then-existing conditions, including our results of operations, financial condition, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

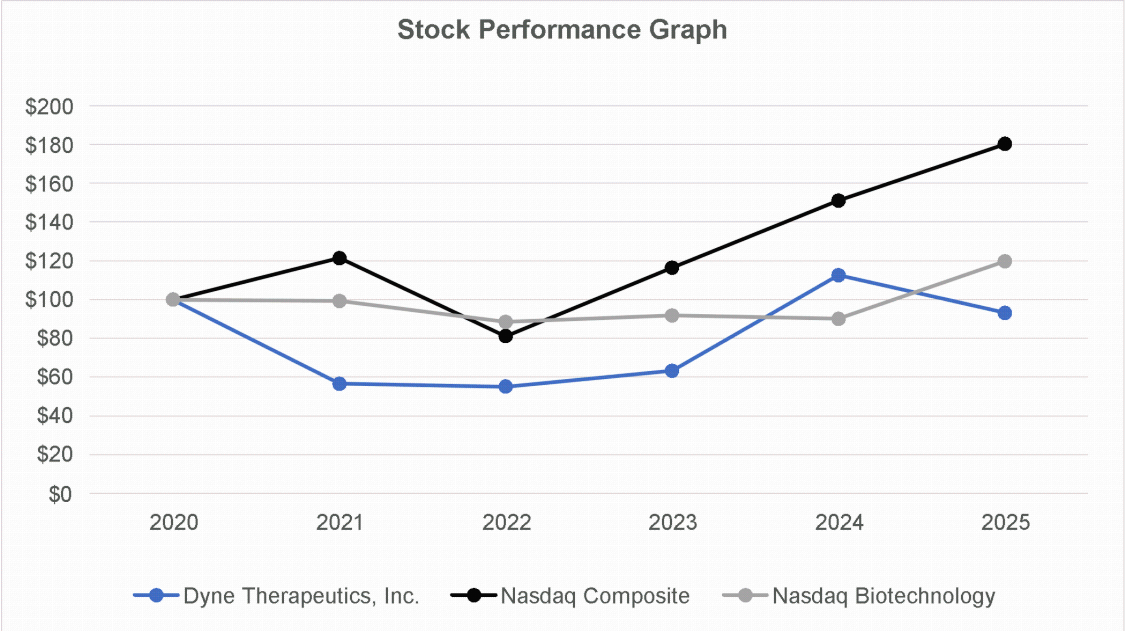
Securities Authorized for Issuance Under Equity Compensation Plans

Information about our equity compensation plans is incorporated by reference herein to Item 12 of this Annual Report on Form 10-K.

Performance Graph

The following performance graph shall not be deemed "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our future filings under the Securities Act of 1933, as amended, or the Securities Act, or the Exchange Act, except to the extent that we specifically incorporate it by reference into such filing.

The following graph compares the performance of our common stock from December 31, 2020 through December 31, 2025 with the performance of the Nasdaq Composite Index and Nasdaq Biotechnology Index. The graph assumes an initial investment of $100 on December 31, 2020 at the closing trading price of $21.00, and that all dividends were reinvested, although dividends have not been declared on our common stock. The stock price performance shown on the graph below is not necessarily indicative of future stock price performance.



Unregistered Sales of Equity Securities

None.

Purchases of Equity Securities

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing at the end of this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage company focused on delivering functional improvement for people living with genetically driven neuromuscular diseases. Our proprietary FORCE platform is designed to leverage the transferrin receptor 1, or TfR1, to deliver targeted therapeutics to muscle tissue and the central nervous system, or CNS. The FORCE platform utilizes an antigen-binding fragment antibody, or Fab, targeting TfR1 conjugated to a payload that we rationally design to target the genetic basis of the disease we are seeking to treat. With our FORCE platform, we have the flexibility to deploy different classes of payloads (such as oligonucleotides and enzymes) with specific mechanisms of action that modify target functions. We currently leverage this modularity to focus on neuromuscular diseases with high unmet need, with etiologic targets and with clear translational potential from preclinical disease models to well-defined clinical development and regulatory pathways.

Using our FORCE platform, we are assembling a broad portfolio of product candidates, including product candidates being developed for Duchenne muscular dystrophy, or DMD, myotonic dystrophy type 1, or DM1, facioscapulohumeral dystrophy, or FSHD, and Pompe disease. In addition, we plan to expand our portfolio through development efforts focused on diseases involving the CNS, rare skeletal muscle diseases, and cardiac and metabolic muscle diseases, including some with larger patient populations. We have identified product candidates for each of our DMD, DM1, FSHD and Pompe programs that are in varying stages of preclinical and clinical development.

DMD

We are developing zeleciment rostudirsen, or z-rostudirsen (also known as DYNE-251), for the treatment of exon 51 skip amenable DMD. Z-rostudirsen is designed to enable the production of near full-length dystrophin in muscle and the CNS to provide functional improvement. Z-rostudirsen has received Breakthrough Therapy, Fast Track and Rare Pediatric Disease designations from the U.S. Food and Drug Administration, or FDA, as well as Orphan Drug designation from the FDA, the European Medicines Agency and the Japanese Ministry of Health, Labour and Welfare for the treatment of individuals with DMD, amenable to exon 51 skipping. Additionally, we are advancing four development candidates (DYNE-253, DYNE-245, DYNE-244 and DYNE-255) for the treatment of DMD amenable to skipping of exons 53, 45, 44, 55, respectively, into IND-enabling studies.

Z-rostudirsen is currently being evaluated in the DELIVER trial, a global Phase 1/2 clinical trial which is designed to be registrational. We plan to submit a biologics license application, or BLA, to the FDA for U.S. Accelerated Approval in the second quarter of 2026 based on dystrophin as a surrogate endpoint. We continue to expect a potential U.S. launch of z-rostudirsen in the first quarter of 2027, assuming FDA grants priority review and FDA approval is received on the anticipated timeline. Further, we plan to initiate a global confirmatory Phase 3 clinical trial of z-rostudirsen in the second quarter of 2026, and we have aligned with the FDA on the Phase 3 trial design and protocol. We continue to pursue approval pathways outside of the United States for z-rostudirsen.

DM1

We are developing zeleciment basivarsen, or z-basivarsen (also known as DYNE-101), for the treatment of DM1. Z-basivarsen is designed to deliver functional improvement in individuals living with DM1 by

reducing toxic nuclear DMPK RNA to release splicing proteins and allow normal mRNA processing. Z-basivarsen has been granted Breakthrough Therapy, Orphan Drug and Fast Track designations by the FDA and Orphan Drug designation by the European Medicines Agency and the Japanese Ministry of Health, Labour and Welfare for the treatment of DM1.

Z-basivarsen is being evaluated in the ACHIEVE trial, a global Phase 1/2 clinical trial which is designed to be registrational. We anticipate a potential U.S. launch of z-basivarsen in the first quarter of 2028, assuming we receive favorable data, priority review is granted, and FDA approval is received on the anticipated timeline. We plan to initiate a Phase 3 clinical trial of z-basivarsen in March 2026, and we have aligned with the FDA on the Phase 3 trial design and protocol. We continue to pursue approval pathways outside of the United States for z-basivarsen.

FSHD

We are developing DYNE-302 for the treatment of FSHD. DYNE-302 is designed to deliver functional improvement in individuals living with FSHD by reducing aberrant DUX4 expression. We are progressing DYNE-302 toward clinical development.

In June 2024 and June 2025, we announced preclinical data for DYNE-302, our product candidate for FSHD, that demonstrated robust and durable DUX4 suppression and functional benefit in a mouse model. We generated these data using an innovative hTfR1/iFLExD mouse model we developed that expresses TfR1 and enables tunable DUX4 induction in skeletal muscle. In hTfR1/iFLExD mice, a single intravenous dose of DYNE-302 resulted in dose-dependent and robust reduction of the DUX4 transcriptome that lasted up to three months, with benefit on muscle structure. DYNE-302 also demonstrated prevention as well as reversal of muscle weakness.

Pompe

We are developing a product candidate, DYNE-401, to deliver an enzyme replacement therapy to address the deficiency of the lysosomal enzyme, GAA, that causes Pompe disease. We engineered FORCE-GAA by leveraging the FORCE platform and evaluated efficacy in vivo using hTfR1/6Neo mice, that were developed by crossing the well-established 6Neo mouse model of Pompe with mice expressing human transferrin receptor 1. Using this approach, intravenous administration cleared glycogen in muscle and the CNS and normalized lysosomal size in hTfR1/6Neo mice. This approach reduced serum neurofilament light chain, a biomarker of axonal injury, providing evidence of benefit in the CNS and displayed superior dose potency compared to GAA alone. Additional data with this approach supported the potential for monthly dosing which is less frequent than approved enzyme replacement therapies for Pompe.

We were incorporated and commenced operations in 2017. Since our incorporation, we have devoted substantially all of our financial resources and efforts to organizing and staffing our company, business planning, raising capital, conducting research and development activities and filing and prosecuting patent applications. We do not have any products for sale and have not generated any revenue from product sales or otherwise. To date, we have principally raised capital through sales of equity securities and our borrowing under our Loan and Security Agreement, or the Loan Agreement, with Hercules Capital, Inc., or Hercules.

Since our inception, we have incurred significant operating losses. Our ability to generate any product revenue or product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more product candidates. For the years ended December 31, 2025, 2024 and 2023, we reported net losses of $446.2 million, $317.4 million and $235.9 million, respectively. As of December 31, 2025, we had an accumulated deficit of $1.4 billion.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We expect that our expenses and capital expenditure requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- advance our product candidates for DMD, DM1, FSHD and Pompe and conduct research programs in additional indications;
- expand the capabilities of our proprietary FORCE platform;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- obtain, expand, maintain, defend and enforce our intellectual property portfolio;
- hire additional clinical, regulatory and scientific personnel;
- establish manufacturing sources for any product candidate we may develop, including the Fab antibody, linkers and therapeutic payload that will comprise the product candidate, and secure supply chain capacity to provide sufficient quantities for preclinical and clinical development and commercial supply;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval; and
- add operational, legal, compliance, financial and management information systems and personnel to support our research, product development and future commercialization efforts, as well as to support our operations as a public company.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for any product candidates we may develop. If we obtain regulatory approval for or otherwise commercialize any product candidates we may develop, we expect to incur significant expenses related to developing our commercialization capabilities to support product sales, marketing and distribution. Further, we expect to continue to incur additional costs associated with operating as a public company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements, and terms loans under our Loan Agreement with Hercules. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed, on favorable terms, or at all. If we fail to raise capital or enter into such agreements or arrangements as and when needed, we may have to significantly delay, reduce or eliminate the development or future commercialization of one or more product candidates we may develop.

Because of the numerous risks and uncertainties associated with product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to raise capital, maintain our research and development efforts, expand our business or continue our operations at planned levels, and as a result we may be forced to substantially reduce or terminate our operations.

We believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses, debt service obligations and capital expenditure requirements into the first quarter of 2028.

We have based our estimate as to how long we expect we will be able to fund our operations, debt service obligations and capital expenditure requirements on assumptions that may prove to be wrong. We could use our available capital resources sooner than we currently expect, in which case we would be

required to obtain additional financing, which may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. See "—Liquidity and capital resources" below. These estimates do not give effect to any additional funding tranches we may obtain access to under our Loan Agreement with Hercules, subject to the achievement of specified clinical, regulatory and commercial milestones, and do not give effect to any revenue we may generate on commercial sales of any products for which we obtain regulatory approval.

Impact of Tariffs

The U.S. administration has announced or imposed a series of tariffs on U.S. trading partners. In response, several countries have threatened or imposed retaliatory measures. While we have not experienced, and do not currently expect to experience, any significant direct impact from these tariffs and retaliatory measures, we could experience a negative impact on our costs of materials and production processes and supply chain disruptions. Supply chain disruptions may impact the development, testing and clinical trials of our product candidates, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. The full extent of the future impact of these and other threatened measures remains uncertain. We continue to monitor these tariffs and retaliatory measures and their possible effects on our business.

Components of our results of operations

Revenue

We have not generated any revenue since our inception and do not expect to generate any revenue from the sale of products until at least 2027, if at all. If our development efforts are successful and we commercialize products, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from product sales, as well as upfront, milestone and royalty payments from such collaboration or license agreements, or a combination thereof.

Research and development expenses

Research and development expenses consist primarily of costs incurred for our research activities and development of our product candidates. These expenses include:

- development and operation of our proprietary FORCE platform;
- employee-related expenses, including salaries, related benefits and stock-based compensation expense, for employees engaged in research and development functions;
- expenses incurred in connection with our research programs and development of our product candidates, including those incurred under agreements with third parties, such as consultants and contract research organizations, or CROs, to conduct preclinical studies and clinical trials;
- the cost of laboratory supplies and acquiring, developing and manufacturing materials for use in our research, preclinical studies and clinical trials, including those incurred under agreements with third parties, such as consultants and contract manufacturing organizations, or CMOs;
- facilities, depreciation and other expenses, which include direct or allocated expenses for rent and maintenance of facilities and insurance; and
- costs related to compliance with regulatory requirements.

We expense research and development costs as incurred. Advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

Our direct external research and development expenses consist of costs that include fees, reimbursed materials and other costs paid to consultants, contractors, CMOs and CROs in connection with our

development, manufacturing and clinical activities. We have not allocated our direct external research and development costs to specific programs or product candidates that are not in clinical development.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. Accordingly, we expect that our research and development expenses will increase substantially as we advance z-rostudirsen and z-basivarsen through clinical trials, in connection with our preclinical and clinical development activities of DYNE-302, our FSHD product candidate, and DYNE-401, our Pompe disease product candidate, and if and as we advance any other product candidates through preclinical studies and clinical trials. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any product candidates we may develop. The successful development of any product candidate is highly uncertain. This is due to the numerous risks and uncertainties associated with product development, including the following:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of programs we decide to pursue and their regulatory paths to market;
- the need to raise funding to complete preclinical and clinical development of any product candidates we may develop;
- our ability to establish new licensing or collaboration arrangements and the progress of the development efforts of third parties with whom we may enter into such arrangements;
- our ability to maintain our current research and development programs and to establish new programs;
- the successful initiation, enrollment and completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- the receipt and related terms of regulatory approvals from applicable regulatory authorities for any product candidates we may develop;
- the availability of specialty raw materials for use in production of any product candidate we may develop;
- establishing agreements with third-party manufacturers for supply of product candidate components for our clinical trials;
- our ability to obtain and maintain patents, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- our ability to protect our other rights in our intellectual property portfolio;
- commercializing product candidates, if and when approved, whether alone or in collaboration with others; and
- obtaining and maintaining third-party insurance coverage and adequate reimbursement for any approved products.

A change in the outcome of any of these variables with respect to the development of any product candidate we may develop could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any product candidate we may develop.

General and administrative expenses

General and administrative expenses consist primarily of employee-related expenses, including salaries, related benefits and stock-based compensation for employees in executive, finance, corporate and business development, commercial and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and administrative consulting services; insurance costs; administrative travel expenses; commercial

readiness activities; and facility-related expenses, which include allocated expenses for rent, depreciation and maintenance of facilities and other operating costs.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our growth strategy. In addition, if we obtain regulatory approval for a product candidate and do not enter into a third-party commercialization collaboration, we expect to incur significant expenses related to building a sales and marketing team to support product sales, marketing and distribution activities.

Interest income

Interest income consists of interest earned on our cash, cash equivalents and marketable securities.

Interest expense

Interest expense consists of amortization of debt issuance costs and discount and interest expense under the Loan Agreement with Hercules.

Other income (expense), net

Other income (expense), net consists of realized gains and losses on sales of marketable securities and foreign currency gains and losses.

Income taxes

Since our inception, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in any year or for our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of December 31, 2025, we had federal and state net operating loss carryforwards of $981.6 million and $1.0 billion, respectively. The federal net operating loss carryforwards are indefinite lived and the state net operating loss carryforwards begin to expire in 2038. As of December 31, 2025, we also had federal and state research and development tax credit carryforwards of $49.0 million and $6.2 million which begin to expire in 2039 and 2033, respectively.

Results of operations

Comparison of the years ended December 31, 2025 and 2024

The following table summarizes our results of operations for the years ended December 31, 2025 and 2024:

	Year Ended December 31,		
(in thousands)	**2025**	**2024**	**Change**
Operating expenses:			
Research and development	$ 398,333	$ 281,406	$ 116,927
General and administrative	69,851	62,480	7,371
Total operating expenses	468,184	343,886	124,298
Loss from operations	(468,184)	(343,886)	(124,298)
Other (expense) income:			
Interest income	29,859	26,922	2,937
Interest expense	(6,192)	—	(6,192)
Other expense, net	(1,697)	(454)	(1,243)
Total other income, net	21,970	26,468	(4,498)
Net loss	$ (446,214)	$ (317,418)	$ (128,796)

Research and development expenses

The following table summarizes our research and development expenses for the years ended December 31, 2025 and 2024:

(in thousands)	Year Ended December 31, 2025	2024	Change
Direct research and development expenses by product candidate:			
Z-rostudirsen (DMD)	$ 98,963	$ 90,468	$ 8,495
Z-basivarsen (DM1)	145,077	74,082	70,995
Unallocated research and development expenses:			
Platform and external research and development	30,831	26,514	4,317
Personnel related (including stock-based compensation)	93,796	69,517	24,279
Facility related and other	29,666	20,825	8,841
Total research and development expenses	$ 398,333	$ 281,406	$ 116,927

Expenses related to z-rostudirsen increased in the year ended December 31, 2025 compared to the year ended December 31, 2024. This was attributable to an increase in clinical trial activity for the DELIVER trial's registrational expansion cohort and Phase 3 start-up costs in advance of anticipated commencement in the second quarter of 2026, as well as increased analytical work to support planned regulatory activities, including preparations for a BLA submission in the second quarter of 2026. Expenses related to z-basivarsen increased in the year ended December 31, 2025 compared to the year ended December 31, 2024. This was attributable to higher manufacturing activity in 2025 related to process performance qualification batches to support a potential future BLA filing for U.S. accelerated approval, higher manufacturing activity to ensure a sufficient clinical supply of drug product for the ongoing ACHIEVE trial and an increase in clinical trial activity for the ACHIEVE trial's registrational expansion cohort and Phase 3 start-up costs in advance of anticipated commencement in the first quarter of 2026.

The increase in platform and external research and development expenses in the year ended December 31, 2025 was primarily due to increased external research activity associated with our preclinical programs and product candidates, primarily DYNE-302 and DYNE-401. The increase in personnel-related expenses was primarily due to increased headcount in our research and development function of 37 employees and higher stock-based compensation expense for awards granted to new hires and existing employees, as well as the acceleration of vesting terms and modification of previously granted awards in connection with entering into separation and consulting agreements with our former chief medical officer in the year ended December 31, 2025. The increase in facility-related and other expenses was primarily due to the increased costs of supporting a larger number of research and development personnel.

General and administrative expenses

The following table summarizes our general and administrative expenses for the years ended December 31, 2025 and 2024:

(in thousands)	Year Ended December 31, 2025	2024	Change
Personnel-related	$ 18,915	$ 11,741	$ 7,174
Stock-based compensation expense	19,607	27,927	(8,320)
Professional and consulting fees	23,490	16,851	6,639
Facility-related and other	7,839	5,961	1,878
Total general and administrative expenses	$ 69,851	$ 62,480	$ 7,371

The increase in personnel-related expenses in the year ended December 31, 2025 compared to the year ended December 31, 2024 was due to increased headcount in our general and administrative function of

30 employees in the year ended December 31, 2025. The decrease in stock-based compensation expense in the year ended December 31, 2025 was primarily the result of acceleration of vesting terms and modification of previously granted awards in connection with entering into separation and consulting agreements with our former chief executive officer, former chief business officer and former chief operating officer in the year ended December 31, 2024. Professional and consulting fees increased in the year ended December 31, 2025 due to the higher consulting costs for commercial preparation activities and to support the overall growth of the organization in 2025. Facility-related and other expenses increased due to the increased costs of supporting a larger number of general and administrative personnel.

Interest income

Interest income for the years ended December 31, 2025 and 2024 was $29.9 million and $26.9 million, respectively, due to interest earned on invested cash balances. The increase in interest income was due to increased cash, cash equivalents and marketable securities balances in the year ended December 31, 2025.

Interest expense

Interest expense for the year ended December 31, 2025 was $6.2 million due to our entry into the Loan Agreement with Hercules in June 2025 and related amendment in December 2025. No interest expense was incurred in the year ended December 31, 2024.

Other expense, net

Other expense for the year ended December 31, 2025 was $1.7 million primarily due to foreign currency gains and losses. Other expense for the year ended December 31, 2024 was $0.5 million primarily due to foreign currency gains and losses.

Comparison of the years ended December 31, 2024 and 2023

Discussion and analysis of the results of operations for the year ended December 31, 2024 as compared to the results of operations for the year ended December 31, 2023 is included under the heading "*Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations*" in our Annual Report on Form 10-K for the year ended December 31, 2024, as filed with the SEC on February 27, 2025.

Liquidity and capital resources

Sources of liquidity

Since our inception, we have incurred significant operating losses. We expect to incur significant expenses and operating losses for the foreseeable future as we support our continued research activities and development of our product candidates and platform. We have not yet commercialized any product candidates, and we do not expect to generate revenue from sales of any product candidates until at least 2027, if at all. To date, we have funded our operations primarily with proceeds from sales of equity securities and our borrowing under the Loan Agreement with Hercules. As of December 31, 2025, we had cash, cash equivalents and marketable securities of $1.1 billion.

In November 2021, we entered into an Open Market Sale Agreement[SM], or the Sales Agreement, with Jefferies LLC, or Jefferies. On March 5, 2024, we filed a universal shelf registration statement on Form S-3, or the 2024 Shelf Registration Statement, pursuant to which we may offer and sell debt securities, common stock, preferred stock, units and/or warrants from time to time at an indeterminate aggregate offering price in one or more offerings. In November 2024, we filed a prospectus supplement relating to the Sales Agreement, pursuant to which, in accordance with the Sales Agreement, we may offer and sell shares of our common stock having an aggregate offering price of up to $300.0 million, which we refer to as our at-the-market offering program. Sales of common stock under the Sales Agreement through Jefferies may be made by any method that is deemed an "at-the-market" offering as defined in Rule 415(a)(4) under the Securities Act.

During the year ended December 31, 2025, we issued and sold an aggregate of 10,660,159 shares of common stock pursuant to the Sales Agreement for aggregate net proceeds of $140.6 million, after deducting commissions and offering expenses payable by us. We sold such shares at a weighted average price of $13.60 per share.

In June 2025, we entered into the Loan Agreement with Hercules, in its capacity as administrative agent and collateral agent and as a lender, and certain other financial institutions that from time to time become parties to the Loan Agreement as lenders, which we refer to collectively as the Lenders. In December 2025, we entered into the First Amendment to the Loan Agreement with Hercules. The Loan Agreement, as amended by the First Amendment, provides for term loans in an aggregate principal amount of up to $275.0 million under multiple tranches, available as follows: (i) an initial term loan tranche funded on the closing date of the Loan Agreement in aggregate principal amount of $100.0 million; (ii) subject to the achievement of specified clinical, regulatory and commercial milestones, and after the borrowing of the second term loan tranche of $50.0 million in December 2025, two additional term loan tranches totaling up to $75.0 million; and (iii) subject to approval by the Lenders' investment committee in their discretion, a final term loan tranche of up to $50.0 million. In the year ended December 31, 2025, we received net proceeds of $148.3 million from the first and second term loan tranches, after deducting debt issuance costs payable by us. Refer to Note 7, "Long-Term Debt" in the accompanying notes to the condensed consolidated financial statements for a discussion of the Loan Agreement with Hercules.

In July 2025, we completed a follow-on public offering, pursuant to which we issued and sold 27,878,788 shares of our common stock. We received net proceeds from the offering of $215.8 million, after deducting underwriting discounts and commissions and offering expenses paid by us.

In December 2025, we completed a follow-on public offering, pursuant to which we issued and sold 21,827,549 shares of our common stock. We received net proceeds from the offering of $377.7 million, after deducting underwriting discounts and commissions and offering expenses paid by us.

Cash flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	Year Ended December 31,	
(in thousands)	**2025**	**2024**
Net cash used in operating activities	$ (403,207)	$ (292,369)
Net cash used in investing activities	(28,751)	(204,076)
Net cash provided by financing activities	890,307	809,895
Net increase in cash, cash equivalents and restricted cash	$ 458,349	$ 313,450

Operating activities

During the year ended December 31, 2025, operating activities used $403.2 million of cash, due to our net loss of $446.2 million and changes in our operating assets and liabilities of $3.4 million, partially offset by non-cash charges of $46.4 million. Net cash used in changes in our operating assets and liabilities primarily consisted of a $12.6 million increase in non-current assets, partially offset by an $8.3 million increase in accounts payable and other liabilities and a $1.0 million decrease in prepaid expenses and other current assets. During the year ended December 31, 2024, operating activities used $292.4 million of cash, due to our net loss of $317.4 million and changes in our operating assets and liabilities of $19.5 million, partially offset by non-cash charges of $44.5 million. Net cash used in changes in our operating assets and liabilities primarily consisted of a $9.0 million decrease in accounts payable and other liabilities and a $10.5 million increase in prepaid expenses and other current assets. Changes in our operating assets and liabilities during these periods were generally due to the growth of our business, increased clinical trial activity, increased manufacturing activities, advancement of our product candidates, the timing of vendor invoices and payments and annual bonus payments.

Investing activities

During the year ended December 31, 2025, net cash used in investing activities was $28.8 million due to purchases of marketable securities of $180.5 million, an advance payment for long-lead equipment of $18.8 million and purchases of property and equipment of $1.9 million, partially offset by maturities of marketable securities of $154.6 million and sales of marketable securities of $17.9 million. During the year ended December 31, 2024, net cash used in investing activities was $204.1 million due to purchases of marketable securities of $317.4 million and purchases of property and equipment of $2.4 million, partially offset by maturities of marketable securities of $105.2 million and sales of marketable securities of $10.6 million

Financing activities

During the year ended December 31, 2025, net cash provided by financing activities was $890.3 million, consisting of $594.0 million in aggregate net proceeds from sales of common stock in our July 2025 and December 2025 offerings, $140.6 million in aggregate net proceeds from sales under our at-the-market offering program, $148.3 million in net proceeds from the first two tranches under the Loan Agreement with Hercules and $8.0 million in proceeds received from stock option exercises. These cash inflows were partially offset by $0.6 million in payment of debt issuance costs.

During the year ended December 31, 2024, net cash provided by financing activities was $809.9 million, consisting of $675.2 million in aggregate net proceeds from sales of common stock in our January 2024 and May 2024 offerings, $97.9 million in aggregate net proceeds from sales under our at-the-market offering program and $36.8 million in proceeds received from stock option exercises.

A discussion of changes in our financial condition for the year ended December 31, 2024 as compared to the year ended December 31, 2023 is included under the heading "*Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations*" in our Annual Report on Form 10-K for the year ended December 31, 2024, as filed with the SEC on February 27, 2025.

Funding requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we advance the clinical development of z-rostudirsen and z-basivarsen, the development of our FSHD and Pompe programs and additional research programs. The timing and amount of our operating expenditures will depend largely on:

- the identification of additional product candidates;
- the scope, progress, costs and results of preclinical and clinical development of any product candidates we may develop;
- the costs, timing and outcome of regulatory review of any product candidates we may develop;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- changes in laws or regulations applicable to any product candidates we may develop, including but not limited to clinical trial requirements for approvals;
- the cost and timing of obtaining materials to produce adequate product supply for any preclinical or clinical development of any product candidate we may develop;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any product candidate we may develop for which we obtain marketing approval;
- the legal costs involved in prosecuting patent applications and enforcing patent claims and other intellectual property claims;
- additions or departures of key scientific or management personnel;

- our ability to establish and maintain collaborations on favorable terms, if at all, as well as the costs and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder; and
- the costs of operating as a public company.

We believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses, debt service obligations, and capital expenditure requirements into the first quarter of 2028. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect the rights of holders of our common stock. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed, on favorable terms, or at all. If we fail to raise capital or enter into such agreements other arrangements as and when needed, we may have to significantly delay, reduce or eliminate the development or future commercialization of one or more of our product candidates we may develop. See Item 1A. “Risk factors” in this Annual Report on Form 10-K for additional risks associated with our substantial capital requirements.

Contractual and other obligations

We enter into contracts in the normal course of business with CROs, CMOs and other third parties for preclinical research studies, clinical trials and testing and manufacturing services. Except for the master manufacturing services agreements described below, these contracts typically do not contain minimum purchase commitments and are generally cancelable by us upon written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation and in the case of certain arrangements with CROs and CMOs may include non-cancelable fees.

We have also entered into a license agreement with the University of Mons under which we are obligated to make specified milestone and royalty payments. The payment obligations under this agreement are contingent upon future events, such as our achievement of specified development, regulatory and commercial milestones, or generating product sales. We are unable to estimate the timing or likelihood of achieving these milestones or generating future product sales. For additional information about our license agreement with the University of Mons and amounts that could become payable in the future under that agreement, see Item 1. “Business—Intellectual Property—License Agreement with the University of Mons” in this Annual Report.

On December 4, 2020, we entered into a lease agreement for office and laboratory space, which was amended in January 2021, March 2021, and June 2021. The lease has a term of 8.5 years that commenced when we gained access to the office and laboratory space in September 2021. Our obligation for the payment of the base rent began in April 2022 and is $0.4 million per month, increasing to $0.5 million per month during the term of the lease. We have two options to extend the term of the lease, each for a period of an additional five years.

On January 15, 2025, we entered into a master manufacturing services agreement with a CMO which secures capacity at the CMO's manufacturing facilities for certain of our product candidates and

components thereof. As of December 31, 2025, we have paid $31.2 million towards non-current assets under this agreement and pursuant to a mutually agreed rolling forecast we have committed to pay an additional $109.5 million in fees through December 2027. In specified termination circumstances, the agreement requires us to pay the CMO for services completed, the cost of the CMO's raw materials that cannot be repurposed and specified cancellation fees. This agreement formalizes and supersedes a letter agreement that we entered into with the CMO on July 18, 2024.

On October 31, 2025, we entered into another master manufacturing services agreement with a CMO which also secures capacity at the CMO's manufacturing facilities for certain of our product candidate components. The agreement obligates us to compensate the CMO for producing certain of our product candidate components pursuant to a mutually agreed rolling forecast. Upon execution, we committed to compensate the CMO at least $28.4 million in fees through March 2027. In specified termination circumstances, the agreement requires us to pay the CMO for services completed, the cost of the CMO's raw materials that cannot be repurposed, capital equipment and certain manufacturing activities previously committed to.

Critical accounting estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

We define our critical accounting policies as those accounting principles generally accepted in the United States of America that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations as well as the specific manner in which we apply those principles. Management has determined that our most critical accounting policies are those relating to accrued research and development expenses and stock-based compensation. As we advance our product candidates into and through clinical development, we expect research and development expenses and, in particular, our accounting for accrued research and development expenses to be an increasingly important critical accounting policy. We believe the following accounting estimates used in the preparation of our consolidated financial statements have the most significant level of estimation uncertainty and have and are reasonably likely to have a material impact on our financial condition and results of operations. For a more detailed description of our significant accounting policies, refer to Note 2, “Summary of Significant Accounting Policies,” in the accompanying notes to the consolidated financial statements.

Accrued research and development expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our service providers and applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of these estimates with the service providers and make adjustments, if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- CROs in connection with the DELIVER and ACHIEVE clinical trials;

- CROs and investigative sites in connection with research activities;
- CMOs in connection with the production of research materials; and
- vendors in connection with preclinical development activities.

We measure the expense recognized based on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CMOs and CROs that supply, conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the achievement of specified milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Stock-based compensation

We measure stock-based awards granted to employees and directors based on fair value on the date of the grant using the Black-Scholes option-pricing model for options with service-based vesting, and we measure awards of restricted stock units based on the closing price of our common stock on the date of grant. Compensation expense for these awards is recognized over the requisite service period, which is generally the vesting period of the respective award. We use the straight-line method to record the expense of awards with service-based vesting conditions. We use the graded-vesting method to record the expense of awards with both service-based and performance-based vesting conditions, commencing when achievement of the performance condition becomes probable. In July 2025, we granted stock options with a combination of service-based vesting and the achievement of certain market conditions.

The fair value of each stock option grant with service-based vesting conditions is estimated on the date of grant using the Black-Scholes option-pricing model, which uses as inputs the fair value of our common stock and assumptions we make for the volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield. The fair value of market-based stock options is estimated using a Monte Carlo valuation method, incorporating various option pricing inputs.

Prior to our IPO, there was no public market for our common stock, and consequently, the estimated fair value of our common stock was determined by our board of directors as of the date of each option grant, with input from management, considering third-party valuations of our common stock as well as our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent third-party valuation through the date of the grant. Since our IPO, we have determined the fair market value of our common stock using the closing price of our common stock as reported on the Nasdaq Global Select Market.

Recently issued accounting pronouncements

Refer to Note 2, "Summary of Significant Accounting Policies," in the accompanying notes to the consolidated financial statements for a discussion of significant accounting policies. There are no recently issued accounting pronouncements that have not yet been adopted that are expected to have a material impact on our financial statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

We are exposed to interest rate market risk as part of our treasury and investment portfolio, which includes cash, cash equivalents, and marketable securities held in readily available checking and money market accounts, as well as debt securities. As part of our investment portfolio, we own financial instruments that are sensitive to market risks. The investment portfolio is used to preserve our capital, provide adequate liquidity and earn returns commensurate with our risk appetite. We invest in instruments that meet the credit quality standards outlined in our investment policy, which also limits the amount of credit exposure to any one issue or type of instrument. These instruments primarily include securities issued by the U.S. government and its agencies, investment-grade corporate bonds and commercial paper, certificates of deposit and money market funds. These investments are denominated in U.S. Dollars and none are held for trading purposes.

For the years ended December 31, 2025, 2024 and 2023, changes in interest rates did not have a material impact on our historical financial position, our business, our financial condition, our results of operations or our cash flows. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our investment portfolio. However, there can be no assurance that changes in interest rates will not have a material adverse impact on us in the future.

Foreign Currency Exchange Risk

We are exposed to market risk related to changes in foreign currency exchange rates from contracts with vendors located outside of the United States, for which certain invoices are denominated in foreign currencies. We currently do not have a foreign currency hedging program. Changes in the relative values of currencies occur regularly and, in some instances, could materially adversely affect our business, our financial condition, our results of operations or our cash flows.

For the years ended December 31, 2025, 2024 and 2023, changes in foreign currency exchange rates did not have a material impact on our historical financial position, our business, our financial condition, our results of operations or our cash flows. Due to the relatively small number of contracts with vendors located outside of the United States denominated in foreign currencies, an immediate 10% change in a foreign currency exchange change would not have a material effect on our historical financial position, our business, our financial condition, our results of operations or our cash flows. However, there can be no assurance that changes in foreign currency exchange rates will not have a material adverse impact on us in the future.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8, together with the report of our independent registered public accounting firm, are appended to this Annual Report on Form 10-K. An index of those financial statements is found in Item 15 of Part IV of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2025. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act means controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange

Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2025, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Our internal control over financial reporting is a process designed under the supervision of our principal executive and principal financial officer to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Management assessed our internal control over financial reporting as of December 31, 2025. Management based its assessment on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2025.

Deloitte & Touche LLP, the independent registered public accounting firm that audited the Consolidated Financial Statements included in this Annual Report on Form 10-K, has issued an audit report on the effectiveness of our internal control over financial reporting as of December 31, 2025, which is included herein.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the three months ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of Dyne Therapeutics, Inc.

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Dyne Therapeutics, Inc. and subsidiary (the "Company") as of December 31, 2025, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2025, of the Company and our report dated March 2, 2026, expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 2, 2026

Item 9B. Other Information.

Director and Officer Trading Arrangements

None of our directors or officers (as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended) adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K) during the fourth quarter of 2025.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspection

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Except to the extent provided below, the information required by this Item 10 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders which we intend to file not later than 120 days after the end of our fiscal year ended December 31, 2025 and is incorporated herein by reference.

We have adopted a written code of business conduct and ethics that applies to our directors, officers, employees and designated agents, including our principal executive officer, principal financial officer, principal accounting officer, or persons performing similar functions. A current copy of the code is posted on the investor relations section of our website, which is located at http://www.dyne-tx.com. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website.

Item 11. Executive Compensation.

The information required by this Item 11 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item 13 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this Item 14 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(1) Consolidated Financial Statements

The following documents are included on pages F-1 through F-23 attached hereto and are filed as part of this Annual Report on Form 10-K.

Report of Independent Registered Public Accounting Firm (PCAOB ID No. 34)	F-2
Consolidated Balance Sheets	F-4
Consolidated Statements of Operations and Comprehensive Loss	F-5
Consolidated Statements of Stockholders' Equity	F-6
Consolidated Statements of Cash Flows	F-7
Notes to Consolidated Financial Statements	F-8

(2) Financial Statement Schedules

All financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

(3) Exhibits

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of the registrant (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K, File No. 001-39509, filed September 21, 2020).
3.2	Amended and Restated Bylaws of the registrant (incorporated by reference to Exhibit 3.2 to the registrant's Annual Report on Form 10-K, File No. 001-39509, filed March 2, 2023).
4.1	Specimen Stock Certificate evidencing the shares of common stock (incorporated by reference to Exhibit 4.1 to the registrant's Registration Statement on Form S-1, File No. 333-248414, filed September 10, 2020).
4.2	Description of Securities Registered Under Section 12 of the Exchange Act (incorporated by reference to Exhibit 4.3 to the registrant's Annual Report on Form 10-K, File No. 001-39509, filed March 4, 2021).
10.1#	2018 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to the registrant's Registration Statement on Form S-1, File No. 333-248414, filed September 10, 2020).
10.2#	Form of Stock Option Agreement under 2018 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the registrant's Registration Statement on Form S-1, File No. 333-248414, filed August 25, 2020).
10.3#	Form of Restricted Stock Agreement under 2018 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the registrant's Registration Statement on Form S-1, File No. 333-248414, filed August 25, 2020).
10.4#	2020 Stock Incentive Plan (incorporated by reference to Exhibit 10.4 to Amendment No. 1 to the registrant's Registration Statement on Form S-1, File No. 333-248414, filed September 10, 2020).

10.5#	Form of Stock Option Agreement under 2020 Stock Incentive Plan (incorporated by reference to Exhibit 10.5 to the registrant's Registration Statement on Form S-1, File No. 333-248414, filed August 25, 2020).
10.6#	Form of Restricted Stock Agreement under 2020 Stock Incentive Plan (incorporated by reference to Exhibit 10.6 to the registrant's Registration Statement on Form S-1, File No. 333-248414, filed August 25, 2020).
10.7#	Form of Restricted Stock Unit Agreement under 2020 Stock Incentive Plan (incorporated by reference to Exhibit 10.7 to the registrant's Registration Statement on Form S-1, File No. 333-248414, filed August 25, 2020).
10.8#	2020 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.8 to Amendment No. 1 to the registrant's Registration Statement on Form S-1, File No. 333-248414, filed September 10, 2020).
10.9#	Form of Indemnification Agreement between the registrant and each of its executive officers and directors (incorporated by reference to Exhibit 10.10 to the registrant's Registration Statement on Form S-1, File No. 333-248414, filed August 25, 2020).
10.10†	License Agreement, dated as of April 27, 2020, by and between the registrant and the University of Mons (incorporated by reference to Exhibit 10.11 to the registrant's Registration Statement on Form S-1, File No. 333-248414, filed August 25, 2020).
10.11#	Offer letter, dated as of December 12, 2019, by and between the registrant and Oxana Beskrovnaya (incorporated by reference to Exhibit 10.17 to the registrant's Registration Statement on Form S-1, File No. 333-248414, filed August 25, 2020).
10.12#	Offer letter, dated as of November 8, 2019, by and between the registrant and Richard Scalzo (incorporated by reference to Exhibit 10.18 to the registrant's Registration Statement on Form S-1, File No. 333-248414, filed August 25, 2020).
10.13#	Amended and Restated Executive Severance and Change in Control Benefits Plan (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q, File No. 001-39509, filed November 3, 2022).
10.14	Lease, by and between Dyne Therapeutics, Inc. and BP3-BOS1 1560 Trapelo Road LLC, dated as of December 4, 2020, as amended (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q, File No. 001-39509 filed August 5, 2021).
10.15	Open Market Sale Agreement℠, dated as of November 4, 2021, by and between the registrant and Jefferies LLC (incorporated by reference to Exhibit 1.2 to the registrant's Registration Statement on Form S-3, File No. 333-260755, filed November 4, 2021).
10.16#	Offer letter, dated as of March 21, 2024, by and between the registrant and John G. Cox (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K, File No. 001-39509, filed March 25, 2024).
10.17#*	2024 Inducement Stock Incentive Plan, as amended.
10.18#	Form of Nonstatutory Stock Option Agreement under 2024 Inducement Stock Incentive Plan (incorporated by reference to Exhibit 10.5 to the registrant's Quarterly Report on Form 10-Q, File No. 001-39509, filed May 2, 2024).

10.19#	Form of Restricted Stock Unit Agreement under 2024 Inducement Stock Incentive Plan (incorporated by reference to Exhibit 10.6 to the registrant's Quarterly Report on Form 10-Q, File No. 001-39509, filed May 2, 2024).
10.20#	Offer letter, dated as of July 23, 2024, by and between the registrant and Douglas Kerr (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q, File No. 001-39509 filed November 12, 2024).
10.21#	Offer letter, dated as of March 18, 2025, by and between the registrant and Erick Lucera (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K, File No. 001-39509, filed March 20, 2025).
10.22#	Labor leasing agreement, dated as of September 3, 2024, by and between the registrant and Globalization Partners Switzerland SA, on behalf of Johanna Friedl-Naderer (incorporated by reference to Exhibit 10.3 to the registrant's Quarterly Report on Form 10-Q, File No. 001-39509 filed May 8, 2025).
10.23#	Separation agreement, dated as of March 31, 2025, by and between the registrant and Richard Scalzo (incorporated by reference to Exhibit 10.4 to the registrant's Quarterly Report on Form 10-Q, File No. 001-39509 filed May 8, 2025).
10.24#	Consulting agreement, dated as of March 31, 2025, by and between the registrant and Richard Scalzo (incorporated by reference to Exhibit 10.5 to the registrant's Quarterly Report on Form 10-Q, File No. 001-39509 filed May 8, 2025).
10.25*†	Loan and Security Agreement, as amended December 8, 2025, by and among the Company, Hercules Capital, Inc., in its capacity as administrative agent and collateral agent for the lenders, and the lenders party thereto.
19.1	Dyne Therapeutics, Inc. Insider Trading Policy (incorporated by reference to Exhibit 19.1 to the registrant's Annual Report on Form 10-K, File No. 001-39509 filed February 27, 2025).
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the registrant's Annual Report on Form 10-K, File No. 001-39509 filed February 27, 2025).
23.1*	Consent of Deloitte & Touche LLP, independent registered public accounting firm, attached hereto as Exhibit 23.1.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

97	Dodd-Frank Compensation Recovery Policy (incorporated by reference to Exhibit 97 to the registrant's Annual Report on Form 10-K, File No. 001-39509 filed March 5, 2024).
101.INS	XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	The cover page from the Company's Annual Report on Form 10-K for the year ended December 31, 2025 has been formatted in Inline XBRL.

* Filed herewith.
† Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.
# Management contract or compensatory plan or arrangement filed in response to Item 15(a)(3) of the Instructions to the Annual Report on Form 10-K.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

DYNE THERAPEUTICS, INC.

Date: March 2, 2026

By: /s/ John G. Cox
John G. Cox
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ John G. Cox John G. Cox	President, Chief Executive Officer and Director (principal executive officer)	March 2, 2026
/s/ Erick Lucera Erick Lucera	Chief Financial Officer and Treasurer (principal financial and accounting officer)	March 2, 2026
/s/ Jason Rhodes Jason Rhodes	Director and Chairman of the Board	March 2, 2026
/s/ Ed Hurwitz Ed Hurwitz	Director	March 2, 2026
/s/ Carlo Incerti, M.D. Carlo Incerti, M.D.	Director	March 2, 2026
/s/ Vikram Karnani Vikram Karnani	Director	March 2, 2026
/s/ Dirk Kersten Dirk Kersten	Director	March 2, 2026
/s/ David Lubner David Lubner	Director	March 2, 2026
/s/ Brian Posner Brian Posner	Director	March 2, 2026
/s/ Catherine Stehman-Breen, M.D. Catherine Stehman-Breen, M.D.	Director	March 2, 2026

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of Dyne Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Dyne Therapeutics, Inc. and subsidiary (the "Company") as of December 31, 2025 and December 31, 2024, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2025, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and December 31, 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2025, based on criteria established in *Internal Control — Integrated Framework (2013)*issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 2, 2026, expressed an unqualified opinion on the Company's internal control over financial reporting.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accrued and Prepaid Research and Development Expense - Refer to Note 2 and 6 to the financial statements

Critical Audit Matter Description

The Company records accrued expenses and prepaid expenses associated with ongoing research and development costs, including costs associated with outsourced agreements for clinical trials with contract research organizations (CROs) and production of research materials with contract manufacturing organizations (CMOs). Estimates of expenses incurred are determined by analyzing progress of the studies, including phase or completion of events, invoices received, payments made, communication with third-party CROs and CMOs, and internal tracking of work completed to date. Expenses incurred in excess of amounts invoiced are recorded as accrued expenses. Payments made in excess of expenses incurred are recorded as prepaid costs. We note that these balances are included in “Accrued Expenses” and “Prepaid expenses and other current assets,” respectively, in the financial statements. We identified auditing the estimates of the extent of work performed by CROs and CMOs as a critical audit matter because of the level of management judgment required and volume of such estimates made by management. This required a high degree of auditor judgment and an increased extent of effort when performing audit procedures to evaluate the reasonableness of management’s estimates.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to accrued and prepaid research and development expenses included the following, among others:

- We tested the design and effectiveness of controls over the estimation of accrued and prepaid research and development expenses.
- For a sample of studies and clinical trials, we performed the following:
  - Inspected the related contracts, purchase orders, statements of work and other contractual documentation.
  - Tested the completeness and accuracy of the underlying data used to develop the estimates.
  - Performed corroborating inquiries with the Company’s research and development personnel.
  - Inspected information from third-party service providers to understand the nature and progress of the studies.
  - Obtained corresponding invoices and evidence of payment to third-party service providers.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 2, 2026

We have served as the Company's auditor since 2020.

Dyne Therapeutics, Inc.
Consolidated Balance Sheets

(in thousands, except share and per share data)	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 893,369	$ 435,449
Marketable securities	217,193	206,819
Prepaid expenses and other current assets	16,025	17,011
Total current assets	1,126,587	659,279
Property and equipment, net	24,029	5,398
Right-of-use assets	20,742	24,615
Restricted cash and other assets	15,600	1,942
Total assets	$ 1,186,958	$ 691,234
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 8,082	$ 6,562
Accrued expenses and other current liabilities	37,548	30,846
Lease liabilities	4,995	4,850
Total current liabilities	50,625	42,258
Long-term debt, net	148,921	—
Lease liabilities, net of current portion	15,283	19,138
Total liabilities	214,829	61,396
Stockholders' equity		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at December 31, 2025 and 2024	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized at December 31, 2025 and 2024; 164,950,540 and 102,318,629 shares issued and outstanding at December 31, 2025 and 2024, respectively	16	10
Additional paid-in capital	2,367,780	1,579,750
Accumulated other comprehensive gain	475	6
Accumulated deficit	(1,396,142)	(949,928)
Total stockholders' equity	972,129	629,838
Total liabilities and stockholders' equity	$ 1,186,958	$ 691,234

The accompanying notes are an integral part of these financial statements.

Dyne Therapeutics, Inc.
Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)	Year Ended December 31, 2025	2024	2023
Operating expenses:			
Research and development	$ 398,333	$ 281,406	$ 210,762
General and administrative	69,851	62,480	31,400
Total operating expenses	468,184	343,886	242,162
Loss from operations	(468,184)	(343,886)	(242,162)
Other (expense) income:			
Interest income	29,859	26,922	7,641
Interest expense	(6,192)	—	—
Other expense, net	(1,697)	(454)	(1,416)
Total other income, net	21,970	26,468	6,225
Net loss	$ (446,214)	$ (317,418)	$ (235,937)
Net loss per share, basic and diluted	$ (3.47)	$ (3.37)	$ (3.95)
Weighted average common shares outstanding, basic and diluted	128,442,723	94,143,565	59,683,851
Comprehensive loss:			
Net loss	$ (446,214)	$ (317,418)	$ (235,937)
Other comprehensive loss:			
Unrealized gains on marketable securities, net	469	6	571
Comprehensive loss	$ (445,745)	$ (317,412)	$ (235,366)

The accompanying notes are an integral part of these financial statements.

Dyne Therapeutics, Inc.
Consolidated Statements of Stockholders' Equity

(in thousands, except share data)	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Stockholders' Equity
Balance at January 1, 2023	55,636,505	$ 6	$ 649,502	$ (571)	$ (396,573)	$ 252,364
Issuance of common stock in at-the-market offering, net of issuance costs of $1.8 million	4,509,063	—	52,369	—	—	52,369
Exercise of stock options	832,906	—	1,953	—	—	1,953
Stock-based compensation	—	—	19,972	—	—	19,972
Vesting of restricted stock units	490,269	—	—	—	—	—
Unrealized gains on marketable securities	—	—	—	571	—	571
Net loss	—	—	—	—	(235,937)	(235,937)
Balance at December 31, 2023	61,468,743	6	723,796	—	(632,510)	91,292
Issuance of common stock in public offering, net of issuance costs of $44.3 million	31,797,500	3	675,177	—	—	675,180
Issuance of common stock in at-the-market offering, net of issuance costs of $3.3 million	3,800,465	1	97,870	—	—	97,871
Exercise of stock options	4,181,133	—	37,043	—	—	37,043
Stock-based compensation	—	—	45,864	—	—	45,864
Vesting of restricted stock units	1,070,788	—	—	—	—	—
Unrealized gains on marketable securities	—	—	—	6	—	6
Net loss	—	—	—	—	(317,418)	(317,418)
Balance at December 31, 2024	102,318,629	10	1,579,750	6	(949,928)	629,838
Issuance of common stock in public offering, net of issuance costs of $39.0 million	49,706,337	5	593,528	—	—	593,533
Issuance of common stock in at-the-market offering, net of issuance costs of $4.4 million	10,660,159	1	140,652	—	—	140,653
Exercise of stock options	990,926	—	7,999	—	—	7,999
Stock-based compensation	—	—	45,851	—	—	45,851
Vesting of restricted stock units	1,274,489	—	—	—	—	—
Unrealized gains on marketable securities	—	—	—	469	—	469
Net loss	—	—	—	—	(446,214)	(446,214)
Balance at December 31, 2025	164,950,540	$ 16	$ 2,367,780	$ 475	$ (1,396,142)	$ 972,129

The accompanying notes are an integral part of these financial statements.

Dyne Therapeutics, Inc.
Consolidated Statements of Cash Flows

(in thousands)	Year Ended December 31, 2025	2024	2023
Cash flows from operating activities:			
Net loss	$ (446,214)	$ (317,418)	$ (235,937)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	45,851	45,864	19,972
Depreciation and amortization expense	2,049	1,673	1,673
Accretion of discount on marketable securities	(1,835)	(3,604)	(1,102)
Loss (gain) on sale of marketable securities	(30)	(35)	23
Non-cash lease expense	163	570	788
Non-cash interest expense	118	—	—
Loss on disposal of property and equipment	95	72	118
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	986	(10,536)	3,337
Other non-current assets	(12,641)	—	—
Accounts payable and other liabilities	8,251	(8,955)	22,970
Net cash used in operating activities	(403,207)	(292,369)	(188,158)
Cash flows from investing activities:			
Purchases of property and equipment	(1,920)	(2,376)	(729)
Advance payment for long-lead equipment	(18,790)	—	—
Purchases of marketable securities	(180,534)	(317,443)	(44,262)
Maturities of marketable securities	154,642	105,180	126,473
Sales of marketable securities	17,851	10,563	1,829
Net cash (used in) provided by investing activities	(28,751)	(204,076)	83,311
Cash flows from financing activities:			
Proceeds from issuance of common stock in public offering, net of issuance costs	593,957	675,180	—
Proceeds from issuance of common stock in at-the-market offering, net of issuance costs	140,653	97,871	52,369
Proceeds from exercise of stock options	7,999	36,844	1,953
Proceeds from issuance of long-term debt, net of issuance costs paid	148,256	—	—
Payment of debt issuance costs	(558)	—	—
Net cash provided by financing activities	890,307	809,895	54,322
Net increase (decrease) in cash, cash equivalents and restricted cash	458,349	313,450	(50,525)
Cash, cash equivalents and restricted cash, beginning of year	437,391	123,941	174,466
Cash, cash equivalents and restricted cash, end of year	$ 895,740	$ 437,391	$ 123,941
Supplemental disclosures of cash flow information:			
Purchase of property and equipment in accounts payable	$ 65	$ —	$ 12
Cash paid for interest	4,339	—	—
Debt issuance costs included in accounts payable or accrued expenses	30	—	—
Offering costs included in accounts payable or accrued expenses	424	—	—
Proceeds from employee stock option exercise in other receivables	—	199	—

The accompanying notes are an integral part of these financial statements.

Dyne Therapeutics, Inc.
Notes to Consolidated Financial Statements

1. Nature of Business and Basis of Presentation

Dyne Therapeutics, Inc. (the “Company”) is a clinical-stage neuromuscular disease company focused on delivering functional improvement for people living with genetically driven neuromuscular diseases. The Company was incorporated in Delaware on December 1, 2017, and has a principal place of business in Waltham, Massachusetts.

The Company is subject to risks and uncertainties common to clinical-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, risks of failure of preclinical studies and clinical trials, the need to obtain marketing approval for its product candidates, fluctuations in operating results, compliance with government regulations, the ability to establish clinical- and commercial-scale manufacturing processes and the ability to secure additional capital to fund operations. Product candidates and programs currently under development require significant research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company’s development efforts are successful and product candidates receive regulatory approval, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

The accompanying consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. Since inception, the Company has funded its operations with proceeds from the sales of equity securities and its term loan with Hercules Capital, Inc. ("Hercules"). The Company expects to continue to generate operating losses for the foreseeable future. The Company expects that its cash, cash equivalents, and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months from the issuance of these consolidated financial statements.

To continue its development efforts, the Company will need to obtain substantial additional funding through public or private equity offerings, debt financings, collaborations, strategic alliances and/or licensing arrangements in order to fund its research and development and ongoing operating expenses. The Company may not be able to obtain financing on acceptable terms, when needed or at all, and the Company may not be able to enter into collaborations, strategic alliances or licensing arrangements. The terms of any financing may adversely affect the holdings or the rights of the Company’s stockholders. Any collaborations, strategic alliances or licensing arrangements may require the Company to relinquish rights to certain of its technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to the Company. If the Company is unable to obtain funding, the Company could be forced to delay, limit, reduce or eliminate some or all of its research and development programs, pipeline expansion or future commercialization efforts or grant rights to develop and market product candidates, which could adversely affect its business prospects. Although management will continue to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations when needed or at all.

2. Summary of Significant Accounting Policies

The accompanying consolidated financial statements reflect the operations of the Company and the Company’s wholly-owned subsidiary, Dyne Therapeutics Securities Corporation. Intercompany balances and transactions have been eliminated in consolidation. The accompanying consolidated financial statements have been prepared in conformity with generally accepted accounting principles (“GAAP”) in the United States of America. Any reference in these notes to applicable guidance is meant to refer to the

authoritative GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Update (“ASU”) of the Financial Accounting Standards Board (“FASB”).

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the accrual of research and development expenses and stock-based compensation expense. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates, as there are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results may differ from those estimates or assumptions.

Concentrations of credit risk and of significant suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company believes the depository institutions in which the cash and cash equivalents are held are of high-credit quality. The Company has adopted an investment policy that limits the amounts the Company may invest in the securities of any single issuer with the exclusion of the U.S. government. The Company has not experienced any credit losses.

The Company is dependent on a small number of third-party suppliers for its drug substance and drug product. In particular, the Company relies, and expects to continue to rely, on third-party suppliers for certain materials and components required for the development of its programs and future production of any product candidates it may develop for its programs. These programs could be adversely affected by a significant interruption in the supply process.

Marketable securities

The Company’s marketable securities consist of commercial paper, certificates of deposit, U.S. Treasury notes and corporate debt securities and are classified as available-for-sale which are reported at fair value. Unrealized gains or losses on available-for-sale debt securities are reported as a component of accumulated other comprehensive loss in stockholders’ equity. Realized gains and losses are based on the specific identification method and are included as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss.

The Company evaluates its marketable securities with unrealized losses for other-than-temporary impairment. When assessing marketable securities for other-than-temporary declines in value, the Company considers such factors as, among other things, how significant the decline in value is as a percentage of the original cost, how long the market value of the investment has been less than its original cost, the Company’s ability and intent to retain the investment for a period of time sufficient to allow for any anticipated recovery in fair value and market conditions in general. If any adjustment to fair value reflects a decline in the value of the investment that the Company considers to be “other than temporary,” the Company reduces the investment to fair value through a charge to the statement of operations and comprehensive loss. No such adjustments were necessary during the periods presented.

Leases

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances presented in the arrangement, including whether the Company controls the use of identified assets. The Company classifies leases with a term greater than one year as either operating or finance leases at the lease commencement date and records a right-of-use assets and current and non-current lease liabilities, as applicable on the balance sheet. The Company has elected not to recognize on the balance sheet leases with terms of one year or less. For

these leases, payments are recognized as expense on a straight-line basis over the lease term. If a lease includes options to extend the lease term, the Company does not assume the option will be exercised in its initial lease term assessment unless there is reasonable certainty that the Company will renew based on an assessment of economic factors present as of the lease commencement date. The Company monitors its plans to renew its material lease each reporting period.

Lease liabilities and the corresponding right-of-use assets are recorded based on the present value of lease payments over the remaining lease term. The present value of future lease payments are discounted using the interest rate implicit in lease contracts if that rate is readily determinable; otherwise the Company utilizes its incremental borrowing rate ("IBR"), which reflects the fixed rate at which the Company could borrow on a collateralized basis over a similar term, the amount of the lease payments in a similar economic environment. After lease commencement and the establishment of a right-to-use asset and operating lease liability, lease expense is recorded on a straight-line basis over the lease term.

The Company enters into contracts that contain both lease and non-lease components. Non-lease components include costs that do not provide a right-to-use a leased asset but instead provide a service, such as maintenance costs. The Company has elected to account for the lease and non-lease components together as a single component for all classes of underlying assets for its operating leases. Variable costs associated with the lease, such as maintenance and utilities, are not included in the measurement of right-to-use assets and lease liabilities but rather are expensed when the events determining the amount of variable consideration to be paid have occurred.

Property and equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the estimated useful life of each asset class.

Costs for capital assets not yet placed into service are capitalized as construction-in-process and depreciated once placed into service. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation and amortization are removed from the accounts and any resulting gain or loss is included in loss from operations. Expenditures for repairs and maintenance which do not improve or extend the life of the respective assets are charged to expense as incurred.

Impairment of long-lived assets

Long-lived assets consist of property and equipment. The Company evaluates the recoverability of its long-lived assets when circumstances indicate that an event of impairment may have occurred. The Company recognizes an impairment loss only if the carrying amount of a long-lived asset is not recoverable based on its undiscounted future cash flows. Impairment is measured based on the difference between the carrying value of the related assets and the fair value of such assets. The Company has not recorded any impairment charges in the periods presented in these financial statements.

Segment information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions on how to allocate resources and assess performance. The Company's chief operating decision maker is the chief executive officer ("CEO"). The CEO views the Company's operations and manages the business as one operating segment.

Research and development costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries and bonuses, stock-based compensation, employee benefits, facilities costs, laboratory supplies, depreciation

and amortization, manufacturing expenses and external costs of vendors engaged to conduct clinical and preclinical development activities as well as the cost of licensing technology.

Upfront payments and milestone payments made for the licensing of technology are expensed as research and development expenses in the period in which they are incurred. Advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are consumed or the services are performed.

Research and manufacturing contract costs and accruals

The Company has entered into various research and development and manufacturing contracts. These agreements are generally cancelable, and related payments are recorded as the corresponding expenses are incurred. The Company records accruals for estimated ongoing costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the research studies and manufacturing activities, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Patent costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Income taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or in the Company's tax returns. Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Fair value measurements

Certain assets and liabilities are carried at fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at

fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Unadjusted quoted prices in active markets that are accessible to the reporting entity at the measurement date for identical assets and liabilities.
- Level 2—Inputs other than quoted prices in active markets for identical assets and liabilities that are observable either directly or indirectly for substantially the full term of the asset or liability. Level 2 inputs include the following:
    - quoted prices for similar assets and liabilities in active markets;
    - quoted prices for identical or similar assets or liabilities in markets that are not active;
    - observable inputs other than quoted prices that are used in the valuation of the asset or liabilities (e.g., interest rate and yield curve quotes at commonly quoted intervals); and
    - inputs that are derived principally from or corroborated by observable market data by correlation or other means.
- Level 3—Unobservable inputs for the assets or liability (i.e., supported by little or no market activity). Level 3 inputs include management's own assumptions about the assumptions that market participants would use in pricing the asset or liability (including assumptions about risk).

Net loss per share

Basic net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding for the period. Diluted net loss is computed by adjusting net loss to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net loss per share is computed by dividing the diluted net loss by the weighted average number of shares of common stock outstanding for the period, including potential dilutive common shares assuming the dilutive effect of common stock equivalents.

The following potentially dilutive common stock equivalents, presented based on amounts outstanding at each period end, were excluded from the computation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	Year Ended December 31,	
	2025	2024
Options to purchase common stock	9,911,043	8,681,473
Unvested restricted stock units	2,438,316	3,722,024
Total	12,349,359	12,403,497

Stock-based compensation

The Company accounts for stock option awards at fair value and measures fair value using the Black-Scholes option-pricing model as of the grant date. For restricted stock unit awards, the fair value is based on the closing price of the Company's common stock on the date of grant. Stock-based compensation costs are recognized as expense over the requisite service period, which is generally the vesting period, on a straight-line basis for all time-vested awards. Forfeitures are recognized as they occur for all awards. For stock option awards with market-based vesting conditions, the fair value is estimated using a Monte Carlo valuation method, incorporating various option pricing inputs and expense is recognized over the remaining service period.

Comprehensive loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. The Company's only element of other comprehensive loss was unrealized gains (losses) on marketable securities.

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Topic 220-40).* The amendments in this update require new disclosures to disaggregate prescribed natural expenses underlying any income statement caption. ASU 2024-03 is effective for annual periods in fiscal years beginning after December 15, 2026, and interim periods thereafter. Early adoption is permitted. ASU 2024-03 applies on a prospective basis for periods beginning after the effective date. However, retrospective application to any or all prior periods presented is permitted. We are currently assessing the impact ASU 2024-03 will have on the consolidated financial statements and disclosures.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740)*. The amendments in this update require enhanced annual income tax disclosures for the effective tax rate reconciliation and income taxes paid. The amendments are effective for the Company in the consolidated financial statements for the year ended December 31, 2025. The Company adopted this ASU for the annual period ended December 31, 2025 and the amendments have been applied retrospectively to all prior periods presented in the financial statements within the footnote disclosure of the reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate. Refer to the rate reconciliation in Note 9 - Income Taxes for more information.

3. Cash, Cash Equivalents and Restricted Cash

Cash includes cash in readily available checking accounts and cash equivalents include money market funds that invest in U.S. Treasury securities and all highly liquid investments maturing within 90 days from the date of purchase.

Amounts included in restricted cash represent amounts pledged as collateral for letters of credit required for security deposits on the Company's leased facilities.

Cash, cash equivalents and restricted cash consisted of the following:

(in thousands)	December 31, 2025	December 31, 2024
Cash and cash equivalents	$ 893,369	$ 435,449
Restricted cash	2,371	1,942
Total	$ 895,740	$ 437,391

4. Fair Value Measurements

The following tables set forth marketable securities for the periods presented:

	As of December 31, 2025			
(in thousands)	Amortized Cost	Unrealized Gains	Unrealized Losses	Total
Commercial paper	7,736	8	—	7,744
Corporate debt securities	175,401	343	(6)	175,738
Certificates of deposit	10,181	9	—	10,190
U.S. Treasury notes	23,400	121	—	23,521
Total	$ 216,718	$ 481	$ (6)	$ 217,193

(in thousands)	As of December 31, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Total
Commercial paper	14,203	8	—	14,211
Corporate debt securities	162,078	131	(114)	162,095
Certificates of deposit	9,369	4	(1)	9,372
U.S. Treasury notes	21,163	7	(29)	21,141
Total	$ 206,813	$ 150	$ (144)	$ 206,819

The following tables set forth by level, within the fair value hierarchy (see Note 2), the assets carried at fair value on a recurring basis for the periods presented:

(in thousands)	Fair Value Measurements as of December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents				
Money market funds	$ 278,133	$ —	$ —	$ 278,133
Marketable securities				
Commercial paper	—	7,744	—	7,744
Corporate debt securities	—	175,738	—	175,738
Certificates of deposit	—	10,190	—	10,190
U.S. Treasury notes	23,521	—	—	23,521
Total	$ 301,654	$ 193,672	$ —	$ 495,326

(in thousands)	Fair Value Measurements as of December 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents				
Money market funds	$ 3,535	$ —	$ —	$ 3,535
Marketable securities				
Commercial paper	—	14,211	—	14,211
Corporate debt securities	—	162,095	—	162,095
Certificates of deposit	—	9,372	—	9,372
U.S. Treasury notes	21,141	—	—	21,141
Total	$ 24,676	$ 185,678	$ —	$ 210,354

The fair value of U.S. government Treasury notes and money market funds were determined by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy. Commercial paper, certificates of deposit and corporate debt securities were valued by the Company using quoted prices in active markets for similar securities, which represent a Level 2 measurement within the fair value hierarchy.

There were no transfers between Level 1, Level 2, or Level 3 during the periods presented.

The following table summarizes the scheduled maturity for the Company's marketable securities for the periods presented:

(in thousands)	December 31, 2025
Maturing in one year or less	$ 156,029
Maturing after one year through two years	61,164
Maturing after two years	—
Total	$ 217,193

Financial instruments not recorded at fair value

The carrying values of cash, cash equivalents, accounts payable and accrued expenses that are reported on the balance sheets approximate their fair value due to the short-term nature of these assets and liabilities. The carrying amount of the Company's Term Loans under the Hercules Agreement, as defined in Note 7, approximate market rates currently available to the Company.

5. Property and Equipment

Property and equipment consisted of the following:

	December 31,	
(in thousands)	**2025**	**2024**
Laboratory equipment	$ 10,897	$ 9,197
Office and computer equipment	2,548	2,355
Construction in process	19,305	619
Property and equipment—at cost	32,750	12,171
Less accumulated depreciation and amortization	(8,721)	(6,773)
Property and equipment—net	$ 24,029	$ 5,398

As of December 31, 2025, the Company was deemed to be the owner, for accounting purposes, of $18.8 million of long-lead equipment to be utilized for future manufacturing at a contract manufacturing organization ("CMO") facility.

Depreciation expense totaled $2.0 million, $1.7 million and $1.7 million for the years ended December 31, 2025, 2024, and 2023 respectively.

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
(in thousands)	**2025**	**2024**
Payroll and benefits	$ 17,097	$ 13,095
Consulting services	1,234	1,608
Legal services	943	742
Research and development	17,085	15,401
Interest	1,189	—
Total	$ 37,548	$ 30,846

7. Long-Term Debt

On June 27, 2025 (the “Closing Date”), the Company entered into the loan agreement with Hercules (as subsequently amended, the “Loan Agreement”), in its capacity as administrative agent and collateral agent (the “Agent”) and as a lender, and certain other financial institutions that from time to time become parties to the Loan Agreement as lenders (collectively, the “Lenders”). On December 8, 2025, the Company entered into the First Amendment to the Loan Agreement with Hercules. The Loan Agreement, as amended by the First Amendment, provides for term loans in an aggregate principal amount of up to $275.0 million under multiple tranches (the “Term Loans”), available as follows: (i) an initial term loan tranche funded on the Closing Date in aggregate principal amount of $100.0 million (the “Initial Tranche”); (ii) subject to the achievement of specified clinical, regulatory and commercial milestones, three additional term loan tranches totaling up to $125.0 million; and (iii) subject to approval by the Lenders’ investment committee, in their discretion, a final term loan tranche of up to $50.0 million.

All unpaid principal and accrued and unpaid interest with respect to the Term Loans is due and payable in full on July 1, 2030 (the “Maturity Date”). The outstanding principal balance of the Term Loans bears

interest at a floating interest rate per annum equal to the Wall Street Journal prime rate, subject to a floor of 7.50%, plus 2.45%. Accrued interest on the outstanding Term Loans is payable monthly. The Company may make payments of interest only until July 1, 2029. The interest only period may be extended until the Maturity Date upon the achievement of specified clinical, regulatory and commercial milestones. At the end of the interest only period, the Company is required to begin repayment of the outstanding principal of the Term Loans in equal monthly installments (or, in a single installment, if the interest-only period has been extended to the Maturity Date).

As collateral for the obligations under the Loan Agreement, the Company has granted to the Agent, for the benefit of the Lenders, a first-priority security interest in substantially all of its property, inclusive of intellectual property, subject to customary permitted liens and other exceptions set forth in the Loan Agreement.

The Loan Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including a minimum cash covenant (the “Minimum Cash Covenant”) requiring the Company to maintain specified levels of cash in accounts subject to a control agreement in favor of the Agent (“Qualified Cash”) during the period commencing on January 1, 2027. The Minimum Cash Covenant will initially be set at 60% of the then outstanding principal balance of the Term Loans, is subject to adjustment and will not be tested at any time when the Company’s market capitalization is greater than $1.65 billion. The Company is also required to maintain minimum net product revenue from the sale of z-rostudirsen and z-basivarsen starting nine months after U.S. Food and Drug Administration approval of z-rostudirsen or z-basivarsen (the “Minimum Revenue Covenant”) if the outstanding principal balance of the Term Loans exceeds $100.0 million. The Minimum Revenue Covenant will not be tested for any month to the extent that for each day during such month either (i) Qualified Cash is at least 100% of the Company’s outstanding obligations under the Loan Agreement or (ii) the Company’s market capitalization is greater than $1.65 billion and Qualified Cash is at least 50% of the Company’s outstanding obligations under the Loan Agreement. Certain negative covenants under the Loan Agreement limit the ability of the Company, among other things, to incur future debt, grant liens, make investments, make acquisitions, distribute dividends and sell assets, subject in each case to certain exceptions.

Upon the occurrence of an event of default, including the failure by the Company to comply with the covenants under the Loan Agreement or the occurrence of a material adverse effect on the business, operations, properties, assets or financial condition of the Company, in each case subject to certain exceptions, and subject to any specified cure periods, all amounts owed by the Company under the Loan Agreement may be declared immediately due and payable by the Agent, and the Agent may foreclose on collateral.

The Loan Agreement requires the Company to pay closing fees, prepayment penalties and an end-of-term charge equal to 5.5% of the amount of Term Loans borrowed, which amount is due at the earlier of prepayment or the Maturity Date. A prepayment penalty applies to any prepayment of the Term Loans prior to the Maturity Date equal to (i) 2.0% of the principal amount prepaid if the prepayment occurs on or prior to the first anniversary of the Closing Date, (ii) 1.5% of the principal amount prepaid if the prepayment occurs after the first anniversary and on or prior to the second anniversary of the Closing Date, and (iii) 0.75% of the principal amount prepaid if the prepayment occurs after the second anniversary through the day before the Maturity Date.

In connection with the execution of the First Amendment to the Loan Agreement, the Company borrowed a second term loan tranche in an aggregate principal amount of $50.0 million. During the year ended December 31, 2025, the average interest rate for the loan was 9.95%.

Unamortized debt discount and issuance costs were recorded as a reduction of the carrying amount on the Term Loans and are amortized as interest expense using the effective-interest method. The Company recorded total debt discount and debt issuance costs of $1.6 million as of December 31, 2025. The Company is accruing the end-of-term charge on its consolidated balance sheet. During the year ended December 31, 2025, the effective interest rate for the loan was 11.5%.

In addition, debt issuance costs of $0.5 million were recorded in restricted cash and other assets as of December 31, 2025.

As of December 31, 2025, the carrying value of the Term Loans approximates its fair value.

The obligations under the Term Loans as of December 31, 2025 consisted of the following (in thousands):

		December 31, 2025
Principal term loan balance	$	150,000
Unamortized debt discount and issuance costs		(1,625)
Accrued end of term fee		546
Long-term debt, net	$	148,921

The annual principal payments due under the Term Loans as of December 31, 2025 were as follows:

Year ending December 31,		(in thousands)
2025	$	—
2026		—
2027		—
2028		—
2029		67,128
2030		82,872
Total	$	150,000

The table of future principal payments excludes the end-of-term charge of 5.5% of the principal amount of the Term Loans borrowed, which is due upon the maturity of the Term Loans.

8. Stockholders' Equity

Common Stock

In November 2021, the Company entered into an Open Market Sale Agreement (the "Sales Agreement") with Jefferies LLC ("Jefferies") as the Company's sales agent. On March 5, 2024, the Company filed a universal shelf registration statement on Form S-3, (the “2024 Shelf Registration Statement”), and included a prospectus relating to the Sales Agreement. Under the 2024 Shelf Registration Statement, the Company may offer and sell debt securities, common stock, preferred stock, units and/or warrants from time to time at an indeterminate aggregate offering price in one or more offerings. In November 2024, the Company filed a prospectus supplement relating to the Sales Agreement, pursuant to which, in accordance with the Sales Agreement, the Company may offer and sell shares of its common stock having an aggregate offering price of up to $300.0 million in an “at-the-market” offering.

During the year ended December 31, 2025, the Company issued and sold an aggregate of 10,660,159 shares of common stock pursuant to the Sales Agreement for aggregate net proceeds of $140.6 million, after deducting commissions and offering expenses payable by the Company. The Company sold such shares at a weighted average price of $13.60 per share.

Atlas Venture and related affiliated entities were beneficial owners of approximately 5.5% of the Company's outstanding common stock as of December 31, 2025. The chairman of the Company's board of directors is a partner at Atlas Venture. On January 27, 2025, the Company issued and sold 1,111,111 shares of common stock through its at-the-market offering program that Atlas Venture and related affiliated entities purchased at a purchase price of $13.50 per share for aggregate gross proceeds of $15.0 million. The shares were purchased at the prevailing market price.

In July 2025, the Company completed a follow-on public offering, pursuant to which the Company issued

and sold 27,878,788 shares of the Company's common stock. The Company received net proceeds of $215.8 million, after deducting underwriting discounts and commissions and offering expenses paid by the Company.

In December 2025, the Company completed a follow-on public offering, pursuant to which the Company issued and sold 21,827,549 shares of the Company's common stock. The Company received net proceeds of $377.7 million, after deducting underwriting discounts and commissions and offering expenses paid by the Company.

2020 Stock Incentive Plan

In August 2020 the Company's board of directors adopted and the Company's stockholders approved the 2020 Stock Incentive Plan (the "2020 Plan"), which became effective on September 16, 2020. The 2020 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards to employees, directors, consultants and advisors of the Company. The 2020 Plan is administered by the Company's board of directors or by a committee appointed by the board of directors. Upon the effectiveness of the 2020 Plan, the Company ceased granting awards under the 2018 Stock Incentive Plan. The number of shares initially reserved for issuance under the 2020 Plan was 4,884,233. The number of shares of common stock reserved for issuance under the 2020 Plan may automatically increase on the first day of each fiscal year, beginning with the fiscal year commencing on January 1, 2021, and continuing for each fiscal year until, and including the fiscal year commencing on, January 1, 2030, in an amount equal to the lower of (1) 5% of the shares of common stock outstanding on such date and (2) an amount determined by the Company's board of directors. On January 1, 2026, 8,247,527 shares were added to the shares reserved for issuance under the 2020 Plan in the sixth of these annual increases.

As of December 31, 2025, 5,391,268 shares remained available for future issuance under the 2020 Plan.

2020 Employee Stock Purchase Plan

In August 2020 the Company's board of directors adopted and the Company's stockholders approved the 2020 Employee Stock Purchase Plan (the "2020 ESPP"), which became effective September 16, 2020. The 2020 ESPP is administered by the Company's board of directors or by a committee appointed by the board of directors. The 2020 ESPP initially provides participating employees with the opportunity to purchase up to an aggregate of 488,414 shares of common stock. The number of shares of common stock reserved for issuance under the 2020 ESPP may automatically increase on the first day of each fiscal year, beginning with the fiscal year commencing on January 1, 2021 and continuing for each fiscal year until, and including the fiscal year commencing on, January 1, 2030, in an amount equal to the lowest of (1) 1,953,656 shares of common stock, (2) 1% of the shares of common stock outstanding on such date, and (3) an amount determined by the board of directors.

As of December 31, 2025, no offering periods have commenced under the 2020 ESPP and 488,414 shares remained available for issuance.

2024 Inducement Stock Incentive Plan

In March 2024, the Company's board of directors adopted the 2024 Inducement Stock Incentive Plan (the "2024 Inducement Plan"). The 2024 Inducement Plan provides for the grant of nonstatutory stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards with respect to an aggregate of 900,000 shares of Common Stock (subject to adjustment as provided in the 2024 Inducement Plan). Awards under the 2024 Inducement Plan may only be granted to new employees who were not previously an employee or director of the Company or are commencing employment with the Company following a bona fide period of non-employment, in either case, as an inducement material to the individual's entering into employment with the Company and in accordance with the requirements of Nasdaq Stock Market Rule 5635(c)(4). In February 2025, the Company's board of directors approved an additional 1,000,000 shares for issuance under the 2024 Inducement Plan. During the year ended December 31, 2025, the Company granted inducement equity awards to four new employees as a

material inducement to acceptance of their respective employment consisting of stock options to purchase up to an aggregate of 544,700 shares of the Company's common stock and restricted stock units with respect to an aggregate of 168,000 shares of the Company's common stock.

As of December 31, 2025, 440,447 shares remained available for future issuance under the 2024 Inducement Plan.

Stock option valuation

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model for stock options with service-based vesting conditions. The fair value is determined based upon the quoted price of the Company's common stock. The Company lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. For options with service-based vesting conditions, the expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future. The fair value of market-based stock options is estimated using a Monte Carlo valuation method, incorporating various option pricing inputs.

The assumptions that the Company used to determine the grant-date fair value of options granted were as follows:

	Year Ended December 31,	
	2025	2024
Expected volatility	67%	66%
Risk-free interest rate	3.65% — 4.52%	3.46% — 4.65%
Expected term (in years)	6	6
Expected dividend yield	—	—

Stock option activity

A summary of the Company's stock option activity and related information for the year ended December 31, 2025 is as follows:

(in thousands, except share and per share data)	Options	Weighted Average Exercise Price	Weighted Average Remaining Life (in years)	Aggregate Intrinsic Value
Outstanding January 1, 2025	8,681,473	$ 19.47	7.3	$ 61,021
Granted	3,783,318	11.66		
Exercised	(990,926)	8.07		
Forfeitures	(1,562,822)	17.62		
Outstanding December 31, 2025	9,911,043	$ 17.92	8.2	$ 52,782
Options exercisable— December 31, 2025	3,621,514	$ 17.97	6.7	$ 18,627
Options vested or expected to vest— December 31, 2025	9,911,043	$ 17.92	8.2	$ 52,782

The intrinsic value of options exercised for the years ended December 31, 2025, 2024 and 2023 totaled $6.6 million, $90.3 million and $8.1 million, respectively. The weighted-average grant date fair value of the options granted during the years ended December 31, 2025, 2024 and 2023 was $7.24 per share, $19.22 per share and $7.28 per share, respectively. As of December 31, 2025, there was $64.9 million of

unrecognized compensation expense, which the Company expects to recognize over a weighted-average period of 2.7 years.

Effective January 2025, the Company entered into a consulting agreement with its former chief medical officer resulting in the modification of previously issued stock option awards. The modification resulted in $0.9 million of additional stock-based compensation expense, all of which was recognized during the three months ended March 31, 2025. The expense was recorded within research and development expenses on the condensed consolidated statements of operations and comprehensive loss. Based on the terms of the consulting agreement, options to purchase 58,659 shares of common stock were forfeited in January 2025.

In July 2025, the Company granted 591,685 stock options, vesting over a three-year term from the grant date and contingent upon the achievement of certain market conditions. The fair value of these market-based stock options was estimated using a Monte Carlo valuation method, incorporating various option pricing inputs. The estimated grant date fair value of $2.8 million will be recognized as expense over the three-year service period. $0.7 million was recognized as expense during the year ended December 31, 2025.

Restricted stock units

A restricted stock unit (“RSU”) represents the right to receive one share of common stock upon vesting of the RSU. The Company grants RSUs with service conditions that vest in four equal annual installments provided that the employee remains employed with the Company, RSUs with service conditions that vest in sixteen equal quarterly installments provided that the employee remains employed with the Company and RSUs with performance-based vesting conditions. As of December 31, 2025, there are no RSUs with performance-based vesting conditions outstanding. The fair value of each RSU is based on the closing price of the Company’s common stock on the date of grant. A summary of the Company’s RSU activity and related information for the year ended December 31, 2025 is as follows:

	Number of Shares Underlying RSUs	Weighted Average Grant Date Fair Value
Issued and unvested as of January 1, 2025	3,722,024	$ 20.49
Granted	760,367	12.35
Vested	(1,274,489)	17.86
Forfeited	(769,586)	17.68
Issued and unvested as of December 31, 2025	2,438,316	$ 20.21

The fair value of RSUs vested during the years ended December 31, 2025, 2024 and 2023 totaled $17.6 million, $32.7 million and $5.6 million, respectively. The weighted average grant date fair value of RSUs granted during the year ended December 31, 2024 was $30.53. As of December 31, 2025, there was $45.0 million of unrecognized compensation costs related to unvested RSUs, which are expected to be recognized over a weighted-average period of 2.7 years.

Effective January 2025, the Company entered into a consulting agreement with its former chief medical officer resulting in the modification of previously issued RSU awards. The modification resulted in the recognition of $0.3 million of additional stock-based compensation expense, all of which was recognized during the three months ended March 31, 2025. The expense was recorded within research and development expenses on the condensed consolidated statements of operations and comprehensive loss. Based on the terms of the consulting agreement, 76,662 RSUs were forfeited in January 2025.

The Company recorded stock-based compensation expense in the following expense categories of its statements of operations:

(in thousands)	Year Ended December 31, 2025	2024	2023
Research and development	$ 26,244	$ 17,937	$ 11,578
General and administrative	19,607	27,927	8,394
Total	$ 45,851	$ 45,864	$ 19,972

9. Income Taxes

There is no provision for income taxes because the Company has historically incurred net operating losses and maintains a full valuation allowance against its deferred tax assets.

The Company adopted ASU No. 2023-09 effective January 1, 2025, retrospectively and prior period disclosures have been adjusted. The new standard requires enhancement and further transparency to certain income tax disclosures, most notably the tax rate reconciliation and income taxes paid. However, as stated above there are no income tax payments. The adoption of ASU 2023-09 did not have a material impact on the Company's consolidated financial statements for the year ended December 31, 2025. A reconciliation of the Company's effective tax rate for tax years ended December 31, 2025, 2024, 2023 is as follows:

	Year Ended December 31, 2025		2024		2023	
	$	%	$	%	$	%
Federal income tax expense at statutory rate	$ (93,705)	21.0%	$ (66,658)	21.0%	$ (49,547)	21.0%
State and local income taxes, net of federal income tax benefit*	13,720	(3.0)	(17,260)	5.5	(31)	—
Tax credits	(17,819)	4.0	(14,120)	4.5	(7,155)	3.0
Changes in valuation allowance	88,206	(19.8)	102,088	(32.2)	54,162	(23.0)
Nontaxable or nondeductible items						
Stock-based compensation	8,937	(2.0)	(18,747)	5.9	1,560	(0.6)
Other	661	(0.2)	14,697	(4.7)	1,011	(0.4)
Effective income tax rate	$ —	0%	$ —	0%	$ —	0%

*: State income tax expense for each period presented is immaterial.

Significant components of the Company's net deferred tax assets at December 31, 2025 and 2024 are as follows:

(in thousands)	Year Ended December 31, 2025	2024
Deferred tax assets:		
Stock-based compensation	$ 2,865	$ 7,684
Net operating loss carryforwards	267,026	86,187
Credit carryforwards	53,928	34,932
Fixed assets	216	267
Accrued expenses	9,381	7,937
Lease liability	5,475	6,469
R&D Capitalization	85,952	151,829
Total deferred tax assets	424,843	295,305
Valuation allowance	(419,243)	(288,667)
Total net deferred tax assets	5,600	6,638
Deferred tax liabilities:		
Right of use asset	(5,600)	(6,638)
Total deferred tax liability	(5,600)	(6,638)
Total deferred tax assets (liabilities)	$ —	$ —

As of December 31, 2025, the Company had federal and state net operating loss carryforwards of $981.6 million and $1.0 billion, respectively. The federal net operating loss carryforwards are indefinite lived and the state net operating loss carryforwards begin to expire in 2038. As of December 31, 2025, the Company also had federal and state research and development tax credit carryforwards $49.0 million and $6.2 million, respectively, which begin to expire in 2039 and 2033, respectively.

Utilization of the net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company completed a Section 382 study of transactions in its stock through December 10, 2025 and concluded that it had experienced ownership changes since inception that it believes under Section 382 and 383 of the Code will result in limitations in its ability to use certain pre-change NOLs and credits. We will continue to analyze the impacts of Section 382 from future transactions in our stock. In addition, the Company may experience subsequent ownership changes as a result of future equity offerings or other changes in the ownership of its stock, some of which are beyond the Company's control. As a result, the amount of the NOLs and tax credit carryforwards presented in these consolidated financial statements could be limited. Similar provisions of state tax law may also apply to limit the use of accumulated state tax attributes.

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of net operating loss carryforwards and research and development tax credit carryforwards. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue from product sales since inception and concluded that it is more likely than not that the Company will not recognize the benefits of its federal and state deferred tax assets. Accordingly, a full valuation allowance has been established against the net deferred tax assets as of December 31, 2025 and 2024. The increase in the valuation allowance for deferred tax assets during the years ended December 31, 2025 and 2024 related primarily to the increase in net operating loss carryforwards.

Changes in the valuation allowance were as follows:

	Year Ended December 31,		
	2025	2024	2023
Valuation allowance at the beginning of year	$ 288,667	$ 145,775	$ 113,622
Decreases recorded as benefit to income tax provision	—	—	—
Increases recorded to income tax provision	130,576	142,892	32,153
Valuation allowance at the end of year	$ 419,243	$ 288,667	$ 145,775

The Company's policy is to record estimated interest and penalties related to uncertain tax positions in income tax expense. The Company has no amounts recorded for any unrecognized tax positions, accrued interest or penalties as of December 31, 2025 and 2024.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by U.S. federal and state jurisdictions, where applicable. There are currently no pending tax examinations. The Company's tax returns are open under statute from 2022 to the present.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted in the U.S. The OBBBA includes significant provisions, such as the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act and restoration of favorable tax treatment for certain business provisions including the expensing of domestic research and development expenditures. The OBBBA did not have a material impact on the Company's consolidated financial statements.

10. Leases

In December 2020, the Company entered into a lease agreement, (the "Lease"), pursuant to which the Company leases 68,187 square feet of office and laboratory space located in Waltham, Massachusetts (the "Premises"). The Lease has a term of eight years and six months and the Company gained access to the Premises in September 2021. The Company has two options to extend the term of the Lease, each for a period of an additional five years; however, those renewals were not considered reasonably certain and were not included in the measurement of the right of use assets or lease obligation.

Summary of lease costs

The Company does not have any finance leases.

The components of lease cost were as follows:

	Year Ended December 31,		
(in thousands)	2025	2024	2023
Operating lease cost	$ 5,707	$ 5,405	$ 5,420
Variable lease cost	2,579	2,309	2,125
Total lease cost	$ 8,286	$ 7,714	$ 7,545

Supplemental disclosure of cash flow information for the lease was as follows:

	Year Ended December 31,		
(in thousands)	2025	2024	2023
Operating cash payments for operating leases	$ 5,544	$ 4,981	$ 4,632

The Company was unable to determine the interest rate implicit in the lease and used the Company's IBR as determined from a market analysis of peer borrowings. The weighted-average remaining lease term and discount rate for the lease was as follows:

	As of December 31,	
	2025	2024
Weighted-average remaining lease term - operating leases	4.25 years	5.25 years
Weighted-average discount rate - operating leases	5.80%	5.80%

Future minimum lease payments under the non-cancelable operating lease consisted of the following as of December 31, 2025:

Year Ending December 31,	(in thousands)
2026	5,130
2027	5,284
2028	5,442
2029	5,606
2030	1,415
Total future minimum lease payments	22,877
Less: imputed interest	(2,599)
Present value of lease liabilities	$ 20,278

Included in the condensed consolidated balance sheet (in thousands)	December 31, 2025
Lease liability	4,995
Lease liability, net of current portion	15,283
Total lease liability	$ 20,278

11. Commitments and Contingencies

Legal proceedings

The Company is not currently party to any material legal proceedings. At each reporting date, the Company evaluates whether a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to any such legal proceedings.

Other contractual obligations

The Company enters into contracts in the normal course of business with third parties for preclinical research studies, clinical trials and testing and manufacturing services. These contracts typically do not contain minimum purchase commitments and are generally cancelable by the Company upon written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including noncancelable obligations of the service providers, up to the date of cancellation and in the case of certain arrangements may include non-cancelable fees.

On January 15, 2025, the Company entered into a master manufacturing services agreement with a CMO which secures capacity at the CMO's manufacturing facilities for certain of the Company's product candidates and components thereof. As of December 31, 2025, the Company paid $31.2 million towards non-current assets under this agreement and pursuant to a mutually agreed rolling forecast the Company has committed to pay an additional $109.5 million in fees through December 2027 for the services described above. In specified termination circumstances, the agreement requires the Company to pay the CMO for services completed, the cost of the CMO's raw materials that cannot be repurposed and specified cancellation fees. This agreement formalizes and supersedes a letter agreement that the Company entered into with the CMO on July 18, 2024.

On October 31, 2025, the Company entered into another master manufacturing services agreement with a CMO which also secures capacity at the CMO's manufacturing facilities for certain of the Company's product candidate components. The agreement obligates the Company to compensate the CMO for producing certain of the Company's product candidate components pursuant to a mutually agreed rolling forecast. The Company has committed to compensate the CMO at least $28.4 million in fees through

March 2027 for the services described above. In specified termination circumstances, the agreement requires the Company to pay the CMO for services completed, the cost of the CMO's raw materials that cannot be repurposed, capital equipment and certain manufacturing activities previously committed to.

12. Segment Reporting

The Company's segment determination is based on the financial results that are regularly evaluated by the Company's chief operating decision maker ("CODM") to determine resource allocation and assess performance. The Company's CODM is its chief executive officer. The Company has one operating and one reportable segment. Net long-lived assets are all physically located in the United States and the total assets of the segment equal the total assets presented on the consolidated balance sheet. The primary financial measure by which the CODM evaluates the business is net loss. The CODM uses net loss to monitor budget versus actual results to assess performance of the segment. A summary of the significant segment expenses reported to the CODM are shown below for the fiscal years ended:

(in thousands)	Year Ended December 31, 2025	2024	2023
Operating Expenses			
Z-rostudirsen (DMD)	$ 98,963	$ 90,468	$ 63,942
Z-basivarsen (DM1)	145,077	74,082	67,056
Platform and external research and development	30,831	26,514	13,169
Personnel related	86,467	63,321	48,907
Stock-based compensation	45,851	45,864	19,972
Facility-related and other operating expenses	29,450	23,001	20,419
Professional and consulting fees	31,545	20,636	8,697
Interest income	(29,859)	(26,922)	(7,641)
Interest expense	6,192	—	—
Other expense, net	1,697	454	1,416
Net loss	$ 446,214	$ 317,418	$ 235,937

The amounts disclosed above for z-rosturdirsen and z-basivarsen include only external expenses.

Exhibit 10.17

2024 INDUCEMENT STOCK INCENTIVE PLAN
OF
DYNE THERAPEUTICS, INC.

1. Purpose

The purpose of this 2024 Inducement Stock Incentive Plan (the "***Plan***") of Dyne Therapeutics, Inc., a Delaware corporation (the "***Company***"), is to advance the interests of the Company's stockholders by enhancing the Company's ability to attract, retain and motivate persons who are expected to make important contributions to the Company with an inducement material for such persons to enter into employment with the Company and by providing such persons with equity ownership opportunities and performance-based incentives that are intended to better align the interests of such persons with those of the Company's stockholders. Except where the context otherwise requires, the term "***Company***" shall include any of the Company's present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Internal Revenue Code of 1986, as amended, and any regulations thereunder (the "***Code***") and any other business venture (including, without limitation, joint venture or limited liability company) in which the Company has a controlling interest, as determined by the Board of Directors of the Company (the "***Board***").

2. Eligibility

Awards under the Plan may only be granted to persons who (a) were not previously an employee or director of the Company or (b) are commencing employment with the Company following a bona fide period of non-employment with the Company, in either case as an inducement material to the individual's entering into employment with the Company and in accordance with the requirements of Nasdaq Stock Market Rule 5635(c)(4). For the avoidance of doubt, neither consultants nor advisors shall be eligible to participate in the Plan. Each person who is granted an Award under the Plan is deemed a "***Participant***." "***Award***" means Options (as defined in Section 5), SARs (as defined in Section 6), Restricted Stock (as defined in Section 7), Restricted Stock Units (as defined in Section 7) and Other Stock-Based Awards (as defined in Section 8).

3. Administration and Delegation

(a) Administration by Board of Directors. The Plan will be administered by the Board. The Board shall have authority to grant Awards and to adopt, amend and repeal such administrative rules, guidelines and practices relating to the Plan as it shall deem advisable. The Board may construe and interpret the terms of the Plan and any Award agreements entered into under the Plan. The Board may correct any defect, supply any omission or reconcile any inconsistency in the Plan or any Award in the manner and to the extent it shall deem expedient and it shall be the sole and final judge of such expediency. All decisions by the Board shall be made in the Board's sole discretion and shall be final and binding on all persons having or claiming any interest in the Plan or in any Award. Notwithstanding the foregoing or anything in the Plan to the contrary, the grant of any Award under the Plan must be approved by the Company's independent compensation committee or a majority of the Company's independent directors (as defined in Nasdaq Stock Market Rule 5605(a)(2)) or otherwise in order to comply with the exemption from the stockholder approval requirement for "inducement grants" provided under Nasdaq Stock Market Rule 5635(c)(4).

(b) Appointment of Committees. To the extent permitted by applicable law, the Board may delegate any or all of its powers under the Plan to one or more committees or subcommittees of the Board (a "***Committee***"). All references in the Plan to the "***Board***" shall mean the Board or a Committee of the Board or the officers referred to in Section 3(c) to the extent that the Board's powers or authority under the Plan have been delegated to such Committee or officers.

(c) Delegation to Officers. Subject to any requirements of applicable law (including as applicable Sections 152 and 157(c) of the General Corporation Law of the State of Delaware), the Board may delegate to one or more officers of the Company the power to grant Awards (subject to any limitations under the Plan) to employees or officers of the Company and to exercise such other powers under the Plan as the Board may determine, provided that the Board shall fix the terms of Awards to be granted by such officers, the maximum number of shares subject to Awards that the officers may grant, and the time period in which

such Awards may be granted; and provided further, that no officer shall be authorized to grant Awards to any "executive officer" of the Company (as defined by Rule 3b-7 under the Securities Exchange Act of 1934, as amended (the "***Exchange Act***")) or to any "officer" of the Company (as defined by Rule 16a-1(f) under the Exchange Act).

4. Stock Available for Awards

(a) Authorized Number of Shares. Subject to adjustment under Section 9, Awards may be made under the Plan for up to 900,000 shares of common stock, $0.0001 par value per share, of the Company (the "***Common Stock***"). Shares issued under the Plan may consist in whole or in part of authorized but unissued shares or treasury shares.

(b) Share Counting. For purposes of counting the number of shares available for the grant of Awards under the Plan under this Section 4:

(1) all shares of Common Stock covered by SARs shall be counted against the number of shares available for the grant of Awards under the Plan; *provided, however*, that (i) SARs that may be settled only in cash shall not be so counted and (ii) if the Company grants an SAR in tandem with an Option for the same number of shares of Common Stock and provides that only one such Award may be exercised (a "***Tandem SAR***"), only the shares covered by the Option, and not the shares covered by the Tandem SAR, shall be so counted, and the expiration of one in connection with the other's exercise will not restore shares to the Plan;

(2) to the extent a Restricted Stock Unit award may be settled only in cash, no shares shall be counted against the shares available for the grant of Awards under the Plan;

(3) if any Award (i) expires or is terminated, surrendered or canceled without having been fully exercised or is forfeited in whole or in part (including as the result of shares of Common Stock subject to such Award being repurchased by the Company at the original issuance price pursuant to a contractual repurchase right) or (ii) results in any Common Stock not being issued (including as a result of an SAR that was settleable either in cash or in stock actually being settled in cash), the unused Common Stock covered by such Award shall again be available for the grant of Awards; *provided, however*, that in the case of the exercise of an SAR, the number of shares counted against the shares available under the Plan shall be the full number of shares subject to the SAR multiplied by the percentage of the SAR actually exercised, regardless of the number of shares actually used to settle such SAR upon exercise and the shares covered by a Tandem SAR shall not again become available for grant upon the expiration or termination of such Tandem SAR; and

(4) shares of Common Stock delivered (by actual delivery, attestation, or net exercise) to the Company by a Participant to (i) purchase shares of Common Stock upon the exercise of an Award or (ii) satisfy tax withholding obligations with respect to Awards (including shares retained from the Award creating the tax obligation) shall be added back to the number of shares available for the future grant of Awards.

5. Stock Options

(a) General. The Board may grant options to purchase Common Stock (each, an "***Option***") and determine the number of shares of Common Stock to be covered by each Option, the exercise price of each Option and the conditions and limitations applicable to the exercise of each Option, including conditions relating to applicable federal or state securities laws, as it considers necessary or advisable. All Options under the Plan shall be Nonstatutory Stock Options. A "Nonstatutory Stock Option" is an Option which is not intended to be an "incentive stock option" within the meaning of Section 422 of the Code.

(b) Exercise Price. The Board shall establish the exercise price of each Option or the formula by which such exercise price will be determined. The exercise price shall be specified in the applicable Option agreement. The exercise price shall be not less than 100% of the Grant Date Fair Market Value (as defined below) of the Common Stock on the date the Option is granted; *provided* that if the Board approves the grant of an Option with an exercise price to be determined on a future date, the exercise price shall be not less than 100% of the Grant Date Fair Market Value on such future date. "***Grant Date Fair Market Value***" of a share of Common Stock for purposes of the Plan will be determined as follows:

(1) if the Common Stock trades on a national securities exchange, the closing sale price (for the primary trading session) on the date of grant; or

(2) if the Common Stock does not trade on any such exchange, the average of the closing bid and asked prices on the date of grant as reported by an over-the-counter marketplace designated by the Board; or

(3) if the Common Stock is not publicly traded, the Board will determine the Grant Date Fair Market Value for purposes of the Plan using any measure of value it determines to be appropriate (including, as it considers appropriate, relying on appraisals) in a manner consistent with the valuation principles under Code Section 409A, except as the Board may expressly determine otherwise.

For any date that is not a trading day, the Grant Date Fair Market Value of a share of Common Stock for such date will be determined by using the closing sale price or average of the bid and asked prices, as appropriate, for the immediately preceding trading day and with the timing in the formulas above adjusted accordingly. The Board can substitute a particular time of day or other measure of "closing sale price" or "bid and asked prices" if appropriate because of exchange or market procedures or can, in its sole discretion, use weighted averages either on a daily basis or such longer period as complies with Code Section 409A.

The Board has sole discretion to determine the Grant Date Fair Market Value for purposes of the Plan, and all Awards are conditioned on the Participants' agreement that the Board's determination is conclusive and binding even though others might make a different determination.

(c) Duration of Options. Each Option shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable Option agreement; *provided, however*, that no Option will be granted with a term in excess of 10 years.

(d) Exercise of Options. Options may be exercised by delivery to the Company of a notice of exercise in a form (which may be electronic, and which may be provided to a third party equity plan administrator) approved by the Company, together with payment in full (in the manner specified in Section 5(e)) of the exercise price for the number of shares for which the Option is exercised. Shares of Common Stock subject to the Option will be delivered by the Company as soon as practicable following exercise.

(e) Payment Upon Exercise. Common Stock purchased upon the exercise of an Option granted under the Plan shall be paid for as follows:

(1) in cash or by check, payable to the order of the Company;

(2) except as may otherwise be provided in the applicable Option agreement or approved by the Board, by (i) delivery of an irrevocable and unconditional undertaking by a creditworthy broker to deliver promptly to the Company sufficient funds to pay the exercise price and any required tax withholding or (ii) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a creditworthy broker to deliver promptly to the Company cash or a check sufficient to pay the exercise price and any required tax withholding;

(3) to the extent provided for in the applicable Option agreement or approved by the Board, by delivery (either by actual delivery or attestation) of shares of Common Stock owned by the Participant valued at their fair market value (valued in the manner determined by (or in a manner approved by) the Board), provided (i) such method of payment is then permitted under applicable law, (ii) such Common Stock, if acquired directly from the Company, was owned by the Participant for such minimum period of time, if any, as may be established by the Board and (iii) such Common Stock is not subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements;

(4) to the extent provided for in the applicable Nonstatutory Stock Option agreement or approved by the Board, by delivery of a notice of "net exercise" to the Company, as a result of which the Participant would receive (i) the number of shares underlying the portion of the Option being exercised, less (ii) such number of shares as is equal to (A) the aggregate exercise price for the portion of the Option being exercised divided by (B) the fair market value of the Common Stock (valued in the manner determined by (or in a manner approved by) the Board) on the date of exercise;

(5) to the extent permitted by applicable law and provided for in the applicable Option agreement or approved by the Board by payment of such other lawful consideration as the Board may determine; or

(6) by any combination of the above permitted forms of payment, to the extent approved by the Board.

(f) Limitation on Repricing. Unless such action is approved by the Company's stockholders, the Company may not (except as provided for under Section 9): (1) amend any outstanding Option granted under the Plan to provide an exercise price per share that is lower than the then-current exercise price per share of such outstanding Option, (2) cancel any outstanding option (whether or not granted under the Plan) and grant in substitution therefor new Awards under the Plan covering the same or a different number of shares of Common Stock and having an exercise price per share lower than the then-current exercise price per share of the cancelled option, (3) cancel in exchange for a cash payment any outstanding Option with an exercise price per share above the then-current fair market value of the Common Stock (valued in the manner determined by (or in a manner approved by) the Board) or (4) take any other action under the Plan that constitutes a "repricing" within the meaning of the rules of the Nasdaq Stock Market or any other exchange or marketplace on which the Company stock is listed or traded (the "***Exchange***").

6. Stock Appreciation Rights

(a) General. The Board may grant Awards consisting of stock appreciation rights ("***SARs***") entitling the holder, upon exercise, to receive an amount of Common Stock or cash or a combination thereof (such form to be determined by the Board) determined by reference to appreciation, from and after the date of grant, in the fair market value of a share of Common Stock (valued in the manner determined by (or in a manner approved by) the Board) over the measurement price established pursuant to Section 6(b). The date as of which such appreciation is determined shall be the exercise date.

(b) Measurement Price. The Board shall establish the measurement price of each SAR and specify it in the applicable SAR agreement. The measurement price shall not be less than 100% of the Grant Date Fair Market Value of the Common Stock on the date the SAR is granted; *provided* that if the Board approves the grant of an SAR effective as of a future date, the measurement price shall be not less than 100% of the Grant Date Fair Market Value on such future date.

(c) Duration of SARs. Each SAR shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable SAR agreement; *provided, however*, that no SAR will be granted with a term in excess of 10 years.

(d) Exercise of SARs. SARs may be exercised by delivery to the Company of a notice of exercise in a form (which may be electronic) approved by the Company, together with any other documents required by the Board.

(e) Limitation on Repricing. Unless such action is approved by the Company's stockholders, the Company may not (except as provided for under Section 9): (1) amend any outstanding SAR granted under the Plan to provide a measurement price per share that is lower than the then-current measurement price per share of such outstanding SAR, (2) cancel any outstanding SAR (whether or not granted under the Plan) and grant in substitution therefor new Awards under the Plan covering the same or a different number of shares of Common Stock and having an exercise or measurement price per share lower than the then-current measurement price per share of the cancelled SAR, (3) cancel in exchange for a cash payment any outstanding SAR with a measurement price per share above the then-current fair market value of the Common Stock (valued in the manner determined by (or in a manner approved by) the Board) or (4) take any other action under the Plan that constitutes a "repricing" within the meaning of the rules of the Exchange.

7. Restricted Stock; Restricted Stock Units

(a) General. The Board may grant Awards entitling recipients to acquire shares of Common Stock ("***Restricted Stock***"), subject to the right of the Company to repurchase all or part of such shares at their issue price or other stated or formula price (or to require forfeiture of such shares if issued at no cost) from the recipient in the event that conditions specified by the Board in the applicable Award are not satisfied

prior to the end of the applicable restriction period or periods established by the Board for such Award. The Board may also grant Awards entitling the recipient to receive shares of Common Stock or cash to be delivered as soon as practicable after the time such Award vests or is settled ("***Restricted Stock Units***") (Restricted Stock and Restricted Stock Units are each referred to herein as a "***Restricted Stock Award***").

(b) Terms and Conditions for All Restricted Stock Awards. The Board shall determine the terms and conditions of a Restricted Stock Award, including the conditions for vesting and repurchase (or forfeiture) and the issue price, if any.

(c) Additional Provisions Relating to Restricted Stock.

(1) Dividends. Unless otherwise provided in the applicable Award agreement, any dividends (whether paid in cash, stock or property) declared and paid by the Company with respect to shares of Restricted Stock ("***Accrued Dividends***") shall be paid to the Participant only if and when such shares become free from the restrictions on transferability and forfeitability that apply to such shares. Each payment of Accrued Dividends will be made no later than the end of the calendar year in which the dividends are paid to stockholders of that class of stock or, if later, the 15th day of the third month following the lapsing of the restrictions on transferability and the forfeitability provisions applicable to the underlying shares of Restricted Stock.

(2) Stock Certificates. The Company may require that any stock certificates issued in respect of shares of Restricted Stock, as well as dividends or distributions paid on such Restricted Stock, shall be deposited in escrow by the Participant, together with a stock power endorsed in blank, with the Company (or its designee). At the expiration of the applicable restriction periods, the Company (or such designee) shall deliver the certificates no longer subject to such restrictions to the Participant or if the Participant has died, to his or her Designated Beneficiary. "***Designated Beneficiary***" means (i) the beneficiary designated, in a manner determined by the Board, by a Participant to receive amounts due or exercise rights of the Participant in the event of the Participant's death or (ii) in the absence of an effective designation by a Participant, the Participant's estate.

(d) Additional Provisions Relating to Restricted Stock Units.

(1) Settlement. As soon as practicable after the vesting of and/or lapsing of any other restrictions (i.e., settlement) with respect to each Restricted Stock Unit, the Participant shall be entitled to receive from the Company such number of shares of Common Stock and/or (if so provided in the applicable Award agreement) an amount of cash equal to the fair market value (valued in the manner determined by (or in a manner approved by) the Board) of such number of shares of Common Stock as are set forth in the applicable Restricted Stock Unit agreement. The Board may provide that settlement of Restricted Stock Units shall be deferred, on a mandatory basis or at the election of the Participant in a manner that complies with Section 409A of the Code.

(2) Voting Rights. A Participant shall have no voting rights with respect to any Restricted Stock Units.

(3) Dividend Equivalents. The Award agreement for Restricted Stock Units may provide Participants with the right to receive an amount equal to any dividends or other distributions declared and paid on an equal number of outstanding shares of Common Stock ("***Dividend Equivalents***"). Dividend Equivalents may be settled in cash and/or shares of Common Stock, as provided in the Award agreement, and shall be subject to the same restrictions on transfer and forfeitability as the Restricted Stock Units with respect to which paid.

8. Other Stock-Based Awards

(a) General. The Board may grant other Awards of shares of Common Stock, and other Awards that are valued in whole or in part by reference to, or are otherwise based on, shares of Common Stock or other property ("***Other Stock-Based Awards***"). Such Other Stock-Based Awards shall also be available as a form of payment in the settlement of other Awards granted under the Plan or as payment in lieu of compensation to which a Participant is otherwise entitled. Other Stock-Based Awards may be paid in shares of Common Stock or cash, as the Board shall determine.

(b) Terms and Conditions. Subject to the provisions of the Plan, the Board shall determine the terms and conditions of each Other Stock-Based Award, including any purchase price applicable thereto.

9. Adjustments for Changes in Common Stock and Certain Other Events

(a) Changes in Capitalization. In the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of Common Stock other than an ordinary cash dividend, (i) the number and class of securities available under the Plan, (ii) the share counting rules set forth in Section 4, (iii) the number and class of securities and exercise price per share of each outstanding Option, (iv) the share and per-share provisions and the measurement price of each outstanding SAR, (v) the number of shares subject to and the repurchase price per share subject to each outstanding award of Restricted Stock and (vi) the share and per-share-related provisions and the purchase price, if any, of each outstanding Restricted Stock Unit award and each outstanding Other Stock-Based Award, shall be equitably adjusted by the Company (or substituted Awards may be made, if applicable) in the manner determined by the Board. Without limiting the generality of the foregoing, in the event the Company effects a split of the Common Stock by means of a stock dividend and the exercise price of and the number of shares subject to an outstanding Option are adjusted as of the date of the distribution of the dividend (rather than as of the record date for such dividend), then an optionee who exercises an Option between the record date and the distribution date for such stock dividend shall be entitled to receive, on the distribution date, the stock dividend with respect to the shares of Common Stock acquired upon such Option exercise, notwithstanding the fact that such shares were not outstanding as of the close of business on the record date for such stock dividend.

(b) Reorganization Events.

(1) Definition. A "***Reorganization Event***" shall mean: (i) any merger or consolidation of the Company with or into another entity as a result of which all of the Common Stock of the Company is converted into or exchanged for the right to receive cash, securities or other property or is cancelled, (ii) any transfer or disposition of all of the Common Stock of the Company for cash, securities or other property pursuant to a share exchange or other transaction or (iii) any liquidation or dissolution of the Company.

(2) Consequences of a Reorganization Event on Awards Other than Restricted Stock.

(A) In connection with a Reorganization Event, the Board may take any one or more of the following actions as to all or any (or any portion of) outstanding Awards other than Restricted Stock on such terms as the Board determines (except to the extent specifically provided otherwise in an applicable Award agreement or another agreement between the Company and the Participant): (i) provide that such Awards shall be assumed, or substantially equivalent Awards shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof), (ii) upon written notice to a Participant, provide that all of the Participant's unvested Awards will be forfeited immediately prior to the consummation of such Reorganization Event and/or that all of the Participant's unexercised Awards will terminate immediately prior to the consummation of such Reorganization Event unless exercised by the Participant (to the extent then exercisable) within a specified period following the date of such notice, (iii) provide that outstanding Awards shall become exercisable, realizable or deliverable, or restrictions applicable to an Award shall lapse, in whole or in part prior to or upon such Reorganization Event, (iv) in the event of a Reorganization Event under the terms of which holders of Common Stock will receive upon consummation thereof a cash payment for each share surrendered in the Reorganization Event (the "***Acquisition Price***"), make or provide for a cash payment to Participants with respect to each Award held by a Participant equal to (A) the number of shares of Common Stock subject to the vested portion of the Award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such Reorganization Event) multiplied by (B) the excess, if any, of (I) the Acquisition Price over (II) the exercise, measurement or purchase price of such Award and any applicable tax withholdings, in exchange for the termination of such Award, (v) provide that, in connection with a liquidation or dissolution of the Company, Awards shall convert into the right to receive liquidation proceeds (if applicable, net of the exercise, measurement or purchase price thereof and any applicable tax withholdings) and (vi) any combination of the foregoing. In taking any of the actions permitted under this Section 9(b)(2), the Board shall not be obligated by the Plan to treat all Awards, all Awards held by a Participant, or all Awards of the same type, identically. (B) Notwithstanding the terms of Section 9(b)(2)(A), in the case of outstanding Restricted Stock Units that are subject to Section 409A of

the Code: (i) if the applicable Restricted Stock Unit agreement provides that the Restricted Stock Units shall be settled upon a "change in control event" within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(i), and the Reorganization Event constitutes such a "change in control event", then no assumption or substitution shall be permitted pursuant to Section 9(b)(2)(A)(i) and the Restricted Stock Units shall instead be settled in accordance with the terms of the applicable Restricted Stock Unit agreement; and (ii) the Board may only undertake the actions set forth in clauses (iii), (iv) or (v) of Section 9(b)(2)(A) if the Reorganization Event constitutes a "change in control event" as defined under Treasury Regulation Section 1.409A-3(i)(5)(i) and such action is permitted or required by Section 409A of the Code; if the Reorganization Event is not a "change in control event" as so defined or such action is not permitted or required by Section 409A of the Code, and the acquiring or succeeding corporation does not assume or substitute the Restricted Stock Units pursuant to clause (i) of Section 9(b)(2)(A), then the unvested Restricted Stock Units shall terminate immediately prior to the consummation of the Reorganization Event without any payment in exchange therefor.

(C) For purposes of Section 9(b)(2)(A)(i), an Award (other than Restricted Stock) shall be considered assumed if, following consummation of the Reorganization Event, such Award confers the right to purchase or receive pursuant to the terms of such Award, for each share of Common Stock subject to the Award immediately prior to the consummation of the Reorganization Event, the consideration (whether cash, securities or other property) received as a result of the Reorganization Event by holders of Common Stock for each share of Common Stock held immediately prior to the consummation of the Reorganization Event (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding shares of Common Stock); *provided, however*, that if the consideration received as a result of the Reorganization Event is not solely common stock of the acquiring or succeeding corporation (or an affiliate thereof), the Company may, with the consent of the acquiring or succeeding corporation, provide for the consideration to be received upon the exercise or settlement of the Award to consist solely of such number of shares of common stock of the acquiring or succeeding corporation (or an affiliate thereof) that the Board determines to be equivalent in value (as of the date of such determination or another date specified by the Board) to the per share consideration received by holders of outstanding shares of Common Stock as a result of the Reorganization Event.

(3) Consequences of a Reorganization Event on Restricted Stock. Upon the occurrence of a Reorganization Event other than a liquidation or dissolution of the Company, the repurchase and other rights of the Company with respect to outstanding Restricted Stock shall inure to the benefit of the Company's successor and shall, unless the Board determines otherwise, apply to the cash, securities or other property which the Common Stock was converted into or exchanged for pursuant to such Reorganization Event in the same manner and to the same extent as they applied to such Restricted Stock; *provided, however*, that the Board may provide for termination or deemed satisfaction of such repurchase or other rights under the instrument evidencing any Restricted Stock or any other agreement between a Participant and the Company, either initially or by amendment. Upon the occurrence of a Reorganization Event involving the liquidation or dissolution of the Company, except to the extent specifically provided to the contrary in the instrument evidencing any Restricted Stock or any other agreement between a Participant and the Company, all restrictions and conditions on all Restricted Stock then outstanding shall automatically be deemed terminated or satisfied.

10. General Provisions Applicable to Awards

(a) Transferability of Awards. Awards shall not be sold, assigned, transferred, pledged or otherwise encumbered by a Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution or pursuant to a qualified domestic relations order, and, during the life of the Participant, shall be exercisable only by the Participant; *provided, however*, that, except with respect to Awards subject to Section 409A of the Code, the Board may permit or provide in an Award for the gratuitous transfer of the Award by the Participant to or for the benefit of any immediate family member, family trust or other entity established for the benefit of the Participant and/or an immediate family member thereof if the Company would be eligible to use a Form S-8 under the Securities Act of 1933, as amended, for the registration of the sale of the Common Stock subject to such Award to such proposed transferee; *provided further*, that the Company shall not be required to recognize any such permitted transfer until such time as such permitted transferee shall, as a condition to such transfer, deliver to the Company a written instrument in form and substance satisfactory to the Company confirming that such transferee shall be bound by all of the terms and

conditions of the Award. References to a Participant, to the extent relevant in the context, shall include references to authorized transferees. For the avoidance of doubt, nothing contained in this Section 10(a) shall be deemed to restrict a transfer to the Company.

(b) Documentation; Press Release. Each Award shall be evidenced in such form (written, electronic or otherwise) as the Board shall determine. Each Award may contain terms and conditions in addition to those set forth in the Plan. Promptly following the grant of an Award hereunder, the Company must disclose in a press release the material terms of the grant, the number of shares involved, and, if required by law or the rules of the Exchange, the identity of the Participant and each Participant, by accepting the Award, consents to the foregoing.

(c) Board Discretion. Except as otherwise provided by the Plan, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award need not be identical, and the Board need not treat Participants uniformly.

(d) Termination of Status. The Board shall determine the effect on an Award of the disability, death, termination or other cessation of employment, authorized leave of absence or other change in the employment or other status of a Participant and the extent to which, and the period during which, the Participant, or the Participant's legal representative, conservator, guardian or Designated Beneficiary, may exercise rights or receive any benefits under the Award.

(e) Withholding. The Participant must satisfy all applicable federal, state, and local or other income and employment tax withholding obligations before the Company will deliver stock certificates or otherwise recognize ownership of Common Stock under an Award. The Company may elect to satisfy the withholding obligations through additional withholding on salary or wages. If the Company elects not to or cannot withhold from other compensation, the Participant must pay the Company the full amount, if any, required for withholding or have a broker tender to the Company cash equal to the withholding obligations. Payment of withholding obligations is due before the Company will issue any shares on exercise, vesting or release from forfeiture of an Award or at the same time as payment of the exercise or purchase price, unless the Company determines otherwise. If provided for in an Award or approved by the Board, a Participant may satisfy the tax obligations in whole or in part by delivery (either by actual delivery or attestation) of shares of Common Stock, including shares retained from the Award creating the tax obligation, valued at their fair market value (valued in the manner determined by (or in a manner approved by) the Company); *provided*, *however*, except as otherwise provided by the Board, that the total tax withholding where stock is being used to satisfy such tax obligations cannot exceed the Company's minimum statutory withholding obligations (based on minimum statutory withholding rates for federal, state and local tax purposes, including payroll taxes, that are applicable to such supplemental taxable income), except that, to the extent that the Company is able to retain shares of Common Stock having a fair market value (determined by, or in a manner approved by, the Company) that exceeds the statutory minimum applicable withholding tax without financial accounting implications or the Company is withholding in a jurisdiction that does not have a statutory minimum withholding tax, the Company may retain such number of shares of Common Stock (up to the number of shares having a fair market value equal to the maximum individual statutory rate of tax (determined by, or in a manner approved by, the Company)) as the Company shall determine in its sole discretion to satisfy the tax liability associated with any Award. Shares used to satisfy tax withholding requirements cannot be subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements.

(f) Amendment of Award. Except as otherwise provided in Sections 5(f) and 6(e) with respect to repricings, the Board may amend, modify or terminate any outstanding Award, including but not limited to, substituting therefor another Award of the same or a different type and changing the date of exercise or realization. The Participant's consent to such action shall be required unless (i) the Board determines that the action, taking into account any related action, does not materially and adversely affect the Participant's rights under the Plan or (ii) the change is permitted under Section 9.

(g) Conditions on Delivery of Stock. The Company will not be obligated to deliver any shares of Common Stock pursuant to the Plan or to remove restrictions from shares previously issued or delivered under the Plan until (i) all conditions of the Award have been met or removed to the satisfaction of the Company, (ii) in the opinion of the Company's counsel, all other legal matters in connection with the

issuance and delivery of such shares have been satisfied, including any applicable securities laws and regulations and any applicable stock exchange or stock market rules and regulations and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Company may consider appropriate to satisfy the requirements of any applicable laws, rules or regulations.

(h) Acceleration. The Board may at any time provide that any Award shall become immediately exercisable in whole or in part, free from some or all restrictions or conditions, or otherwise realizable in whole or in part, as the case may be.

11. Miscellaneous

(a) No Right To Employment or Other Status. No person shall have any claim or right to be granted an Award by virtue of the adoption of the Plan, and the grant of an Award shall not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan, except as expressly provided in the applicable Award.

(b) No Rights As Stockholder; Clawback Policy. Subject to the provisions of the applicable Award, no Participant or Designated Beneficiary shall have any rights as a stockholder with respect to any shares of Common Stock to be issued with respect to an Award until becoming the record holder of such shares. In accepting an Award under the Plan, a Participant agrees to be bound by any clawback policy the Company has in effect or may adopt in the future, including the Company's Dodd-Frank Compensation Recovery Policy.

(c) Effective Date. The Plan shall become effective on the date on which it is adopted by the Board. It is expressly intended that approval of the Company's stockholders not be required as a condition to the effectiveness of the Plan, and the Plan's provisions shall be interpreted in a manner consistent with such intent for all purposes.

(d) Amendment of Plan. The Board may amend, suspend or terminate the Plan or any portion thereof at any time provided that no amendment that would require stockholder approval under the rules of the Exchange may be made effective unless and until the Company's stockholders approve such amendment. Unless otherwise specified in the amendment, any amendment to the Plan adopted in accordance with this Section 11(d) shall apply to, and be binding on the holders of, all Awards outstanding under the Plan at the time the amendment is adopted, provided the Board determines that such amendment, taking into account any related action, does not materially and adversely affect the rights of Participants under the Plan.

(e) Authorization of Sub-Plans (including for Grants to non-U.S. Employees). The Board may from time to time establish one or more sub-plans under the Plan for purposes of satisfying applicable securities, tax or other laws of various jurisdictions. The Board shall establish such sub-plans by adopting supplements to the Plan containing (i) such limitations on the Board's discretion under the Plan as the Board deems necessary or desirable or (ii) such additional terms and conditions not otherwise inconsistent with the Plan as the Board shall deem necessary or desirable. All supplements adopted by the Board shall be deemed to be part of the Plan, but each supplement shall apply only to Participants within the affected jurisdiction and the Company shall not be required to provide copies of any supplement to Participants in any jurisdiction which is not the subject of such supplement.

(f) Compliance with Section 409A of the Code. If and to the extent (i) any portion of any payment, compensation or other benefit provided to a Participant pursuant to the Plan in connection with his or her employment termination constitutes "nonqualified deferred compensation" within the meaning of Section 409A of the Code and (ii) the Participant is a specified employee as defined in Section 409A(a)(2)(B)(i) of the Code, in each case as determined by the Company in accordance with its procedures, by which determinations the Participant (through accepting the Award) agrees that he or she is bound, such portion of the payment, compensation or other benefit shall not be paid before the day that is six months plus one day after the date of "separation from service" (as determined under Section 409A of the Code) (the "***New Payment Date***"), except as Section 409A of the Code may then permit. The aggregate of any payments that otherwise would have been paid to the Participant during the period between the date of separation from service and the New Payment Date shall be paid to the Participant in a lump sum on such New Payment Date, and any remaining payments will be paid on their original schedule.

The Company makes no representations or warranty and shall have no liability to the Participant or any other person if any provisions of or payments, compensation or other benefits under the Plan are determined to constitute nonqualified deferred compensation subject to Section 409A of the Code but do not to satisfy the conditions of that section.

(g) Limitations on Liability. Notwithstanding any other provisions of the Plan, no individual acting as a director, officer, employee or agent of the Company will be liable to any Participant, former Participant, spouse, beneficiary, or any other person for any claim, loss, liability, or expense incurred in connection with the Plan, nor will such individual be personally liable with respect to the Plan because of any contract or other instrument he or she executes in his or her capacity as a director, officer, employee or agent of the Company. The Company will indemnify and hold harmless each director, officer, employee or agent of the Company to whom any duty or power relating to the administration or interpretation of the Plan has been or will be delegated, against any cost or expense (including attorneys' fees) or liability (including any sum paid in settlement of a claim with the Board's approval) arising out of any act or omission to act concerning the Plan unless arising out of such person's own fraud or bad faith.

(h) Governing Law. The provisions of the Plan and all Awards made hereunder shall be governed by and interpreted in accordance with the laws of the State of Delaware, excluding choice-of-law principles of the law of such state that would require the application of the laws of a jurisdiction other than the State of Delaware.

DYNE THERAPEUTICS, INC.

Amendment No. 1 to
2024 Inducement Stock Incentive Plan

Dyne Therapeutics, Inc.'s (the "Company") 2024 Inducement Stock Incentive Plan (the "Inducement Plan"), pursuant to Section 1l(d) thereof, is hereby amended as follows:

1. Section 4(a) of the Inducement Plan be, and hereby is, amended by increasing the maximum number of shares of common stock, $0.0001 par value per share, of the Company (the "Common Stock") reserved under the Inducement Plan for Awards (as defined in the Inducement Plan) from 900,000 shares of Common Stock to 1,900,000 shares of Common Stock.

Adopted by the Board of Directors: February 26, 2025

DYNE THERAPEUTICS, INC.

Amendment No. 2 to
2024 Inducement Stock Incentive Plan

Dyne Therapeutics, Inc.'s (the "Company") 2024 Inducement Stock Incentive Plan (the "Inducement Plan"), pursuant to Section 1l(d) thereof, is hereby amended as follows:

2. Section 4(a) of the Inducement Plan be, and hereby is, amended by increasing the maximum number of shares of common stock, $0.0001 par value per share, of the Company (the "Common Stock") reserved under the Inducement Plan for Awards (as defined in the Inducement Plan) from 1,900,000 shares of Common Stock to 4,100,000 shares of Common Stock.

Adopted by the Board of Directors: February 26, 2026

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

Exhibit 10.25

FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT (this "Amendment"), dated as of December 8, 2025, is entered into by and among DYNE THERAPEUTICS, INC., a Delaware corporation ("Borrower"), the several banks and other financial institutions or entities parties to this Amendment (each, a "Lender", and collectively, "Lenders"), and HERCULES CAPITAL, INC., a Maryland corporation, in its capacity as administrative agent and collateral agent for itself and the Lenders (together with its successors and assigns, in such capacity, the "Agent").

A. Borrower, Lenders and Agent are parties to that certain Loan and Security Agreement, dated as of June 27, 2025 (as may be amended, restated, supplemented or otherwise modified from time to time prior to the date of this Amendment, the "Loan Agreement").

B. Borrower has requested that Agent and Lenders agree to certain amendments to the Loan Agreement. Agent and Lenders have agreed to such request, subject to the terms and conditions hereof.

SECTION 1Definitions; Interpretation.

(a) **Terms Defined in Loan Agreement**. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan Agreement (as amended by this Amendment).

(b) **Rules of Construction**. The rules of construction in Sections 1.3, 1.4 and 1.5 of the Loan Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION 2Amendments to the Loan Agreement.

(a) Upon the occurrence of the First Amendment Effective Date (as defined below), the Loan Agreement (including the addenda, exhibits and schedules thereto) shall hereby be amended by (a) deleting the stricken text (indicated textually in the same manner as the following example: ~~stricken text~~) and (b) adding the double underlined text (indicated textually in the same manner as the following example: double-underlined text) as set forth in the marked copy of the Loan Agreement attached hereto as Exhibit A. Exhibit B attached hereto sets forth a clean copy of the Loan Agreement as amended hereby in accordance with the foregoing.

(b) **References Within Loan Agreement**. Each reference in the Loan Agreement to "this Agreement" and the words "hereof," "herein," "hereunder", or words of like import, shall mean and be a reference to the Loan Agreement as amended by this Amendment.

SECTION 3Conditions of Effectiveness. This Amendment shall be effective on the date of satisfaction of the following conditions (such date, the "First Amendment Effective Date"):

(a) Agent shall have received:

(i) this Amendment, executed by Agent, the Lenders, and Borrower;

(ii) a certified copy of the resolutions of Borrower's Board of Directors evidencing approval of the transactions evidenced by this Amendment;

(iii) an Advance Request for the Tranche 2 Advance in a principal amount of Fifty Million Dollars ($50,000,000) made on the First Amendment Effective Date, duly executed by Borrower's Chief Executive Officer or Chief Financial Officer; provided that the Agent and Lenders hereby waive the requirement under Section 2.2(c) of the Loan Agreement to provide an Advance Request at least five (5) Business Days before the First Amendment Effective Date;

(iv) evidence satisfactory to Agent that Borrower has achieved the Data Milestone I; *provided* that such Data Milestone I shall be deemed to be achieved upon Agent's execution of this Amendment; and

(v) such other documents as Agent may reasonably request.

(b) Immediately after giving effect to this Amendment, the representations and warranties contained in Section 4 hereof shall be true and correct on and as of the First Amendment Effective Date as though made on and as of such date.

(c) Borrower shall have paid (i) the Subsequent Tranche Facility Charge in an amount equal to [**] Dollars ($[**]), (ii) all invoiced costs and expenses then due in accordance with Section 6(d) and (iii) all other fees, costs and expenses, if any, due and payable as of the date hereof under the Loan Agreement.

SECTION 4Representations and Warranties. To induce Agent and Lenders to enter into this Amendment, Borrower hereby confirms, as of the date hereof, (a) that the representations and warranties made by it in the Loan Agreement and in the other Loan Documents are true and correct in all material respects, except to the extent such representations and warranties expressly relate to an earlier date, and (b) that no Default or Event of Default has occurred and is continuing; (c) no event that has had or could reasonably be expected to have a Material Adverse Effect has occurred and is continuing; (d) Agent has and shall continue to have a valid, enforceable and perfected first-priority lien, subject only to Permitted Liens, on and security interests in the Collateral and all other collateral heretofore granted by Borrower to Lenders, pursuant to the Loan Documents or otherwise granted to or held by Lenders; (e) the agreements and obligations of Borrower contained in the Loan Documents and in this Amendment constitute the legal, valid and binding obligations of Borrower, enforceable against Borrower in accordance with their respective terms, except as the enforceability thereof may be limited by bankruptcy, insolvency, reorganization, receivership, moratorium or other laws affecting creditors' rights generally and by general principles of equity; and (f) the execution, delivery and performance of this Amendment by Borrower will not (i) violate any provision of Borrower's Organizational Documents or any material law, regulation, order, injunction, judgment, decree or writ to which Borrower is subject in any material respect, (ii) violate any Material Agreement, (iii) require the consent or approval of any other Person or Governmental Authority which has not already been obtained or (iv) result in the creation or imposition of any Lien on any of the Collateral, other than Permitted Liens.

SECTION 5Release. In consideration of the agreements of Agent and each Lender contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Borrower, on behalf of itself and its successors, assigns, and other legal representatives, hereby to the extent possible under applicable law fully, absolutely, unconditionally and irrevocably releases, remises and forever discharges Agent and each Lender, and its successors and assigns, and its present and former shareholders, affiliates, subsidiaries, divisions, predecessors, directors, officers, attorneys, employees, agents and other representatives (Agent, Lenders and all such other persons being hereinafter referred to collectively as the "**Releasees**" and individually as a "**Releasee**"), of and from all demands, actions, causes of action, suits, covenants, contracts, controversies, agreements, promises, sums of money, accounts, bills, reckonings, damages and any and all other claims, counterclaims, defenses, rights of set-off, demands and liabilities whatsoever of every name and nature, known or unknown, suspected or

unsuspected, both at law and in equity, which Borrower, or any of its successors, assigns, or other legal representatives may now or hereafter own, hold, have or claim to have against the Releasees or any of them for, upon, or by reason of any circumstance, action, cause or thing whatsoever which arises at any time on or prior to the day and date of this Amendment, for or on account of, or in relation to, or in any way in connection with the Loan Agreement, or any of the other Loan Documents or transactions thereunder or related thereto. Borrower understands, acknowledges and agrees that the release set forth above may be pleaded as a full and complete defense and may be used as a basis for an injunction against any action, suit or other proceeding which may be instituted, prosecuted or attempted in breach of the provisions of such release. Borrower agrees that no fact, event, circumstance, evidence or transaction which could now be asserted or which may hereafter be discovered shall affect in any manner the final, absolute and unconditional nature of the release set forth above.

SECTION 6Miscellaneous.

(a) **Loan Documents Otherwise Not Affected; Reaffirmation; No Novation**.

(i) Except as expressly amended pursuant hereto or referenced herein, the Loan Agreement and the other Loan Documents shall remain unchanged and in full force and effect and are hereby ratified and confirmed in all respects. The Lenders' and Agent's execution and delivery of, or acceptance of, this Amendment shall not be deemed to create a course of dealing or otherwise create any express or implied duty by any of them to provide any other or further amendments, consents or waivers in the future.

(ii) Borrower hereby expressly (1) reaffirms, ratifies and confirms its Secured Obligations under the Loan Agreement and the other Loan Documents, (2) reaffirms, ratifies and confirms the grant of security under Section 3 of the Loan Agreement, (3) reaffirms that such grant of security in the Collateral secures all Secured Obligations under the Loan Agreement, as of the date hereof, and with effect from (and including) the First Amendment Effective Date, such grant of security in the Collateral: (x) remains in full force and effect notwithstanding the amendments expressly referenced herein; and (y) secures all Secured Obligations under the Loan Agreement, as amended by this Amendment, and the other Loan Documents, (4) agrees that this Amendment shall be a "Loan Document" under the Loan Agreement, and (5) agrees that the Loan Agreement (as amended by this Amendment) and each other Loan Document shall remain in full force and effect following any action contemplated in connection herewith.

(iii) This Amendment is not a novation and the terms and conditions of this Amendment shall be in addition to and supplemental to all terms and conditions set forth in the Loan Documents. Nothing in this Amendment is intended, or shall be construed, to constitute an accord and satisfaction of Borrower's Secured Obligations under or in connection with the Loan Agreement and any other Loan Document or to modify, affect or impair the perfection or continuity of Agent's security interest in (on behalf of itself and the Lenders) security titles to or other liens on any Collateral for the Secured Obligations.

(b) **Conditions**. For purposes of determining compliance with the conditions specified in Section 3, each Lender that has signed this Amendment shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to the Lenders unless Agent shall have received notice from such Lender prior to the date hereof specifying its objection thereto.

(c) **No Reliance**. Borrower hereby acknowledges and confirms to Agent and Lenders that Borrower is executing this Amendment on the basis of its own investigation and for its own reasons without

reliance upon any agreement, representation, understanding or communication by or on behalf of any other Person.

(d) **Costs and Expenses**. Borrower agrees to pay to Agent on the date hereof the fees and expenses of Agent and each Lender party hereto, and the fees and disbursements of counsel to Agent and each Lender party hereto in connection with the negotiation, preparation, execution and delivery of this Amendment and any other documents to be delivered in connection herewith on the date hereof, in each case, in accordance with Section 11.12 of the Loan Agreement.

(e) **Binding Effect**. The provisions of this Amendment shall insure to the benefit of and be binding on each party and its permitted assigns (if any).

(f) **Governing Law.** THIS AMENDMENT SHALL BE GOVERNED BY, AND CONSTRUED AND ENFORCED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK, EXCLUDING CONFLICT OF LAWS PRINCIPLES THAT WOULD CAUSE THE APPLICATION OF LAWS OF ANY OTHER JURISDICTION.

(g) **Complete Agreement; Amendments**. This Amendment and the Loan Documents constitute the entire agreement and understanding of the parties hereto in respect of the subject matter hereof and thereof, and supersede and replace in their entirety any prior proposals, term sheets, non-disclosure or confidentiality agreements, letters, negotiations or other documents or agreements, whether written or oral, with respect to the subject matter hereof or thereof.

(h) **Severability of Provisions.** Whenever possible, each provision of this Amendment shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Amendment shall be prohibited by or invalid under such law, such provision shall be ineffective only to the extent and duration of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Amendment.

(i) **Counterparts**. This Amendment may be executed in any number of counterparts, and by different parties hereto in separate counterparts, each of which, when so delivered, shall be deemed an original, but all of which counterparts shall constitute but one and the same instrument.

(j) **Electronic Execution of Certain Other Documents**. The words “execution,” “execute”, “signed,” “signature,” and words of like import in or related to any document to be signed in connection with this Amendment and the transactions contemplated hereby (including without limitation assignments, assumptions, amendments, waivers and consents) shall be deemed to include electronic signatures, the electronic matching of assignment terms and contract formations on electronic platforms approved by Agent, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

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IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment, as of the date first above written.

BORROWER:

1. DYNE THERAPEUTICS, INC.

2. Signature: /s/ Erick Lucera_____

3. Print Name: Erick Lucera

4. Title: Chief Financial Officer

[SIGNATURES CONTINUE ON THE NEXT PAGE]

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AGENT:

HERCULES CAPITAL, INC.

Signature: /s/ Seth Meyer
Print Name: Seth Meyer
Title: Chief Financial Officer

LENDERS:

HERCULES CAPITAL, INC.

Signature: /s/ Seth Meyer
Print Name: Seth Meyer
Title: Chief Financial Officer

HERCULES PRIVATE CREDIT FUND 1 L.P.
By: Hercules Private Global Venture Growth Fund GP I LLC, its General Partner

Signature: /s/ Seth Meyer
Print Name: Seth Meyer
Title: Authorized Signatory

HERCULES PRIVATE GLOBAL VENTURE
GROWTH FUND I L.P.
By: Hercules Private Global Venture Growth Fund GP I LLC, its General Partner

Signature: /s/ Seth Meyer
Print Name: Seth Meyer
Title: Authorized Signatory

HERCULES VENTURE GROWTH CREDIT
OPPORTUNITIES FUND I L.P.
By: Hercules Venture Growth Credit Opportunities Fund GP I LLC, its General Partner

Signature: /s/ Seth Meyer
Print Name: Seth Meyer
Title: Authorized Signatory

IF " DOCVARIABLE "SWDocIDLocation" 4096" = "1" " DOCPROPERTY "SWDocID" ActiveUS 214848224v.1" ""

HERCULES CAPITAL IV, L.P.
By: Hercules Technology SBIC Management, LLC, its General Partner
By: Hercules Capital, Inc., its Manager

Signature: ___/s/ Seth Meyer_____
Print Name: Seth Meyer
Title: Chief Financial Officer

HERCULES SBIC V, L.P.
By: Hercules Technology SBIC Management, LLC, its General Partner
By: Hercules Capital, Inc., its Manager

Signature: ___/s/ Seth Meyer_____
Print Name: Seth Meyer
Title: Chief Financial Officer

IF " DOCVARIABLE "SWDocIDLocation" 4096" = "1" " DOCPROPERTY "SWDocID" ActiveUS 214848224v.1" ""

EXHIBIT A

LOAN AND SECURITY AGREEMENT

THIS LOAN AND SECURITY AGREEMENT is made and dated as of June 27, 2025 and is entered into by and among DYNE THERAPEUTICS, INC., a Delaware corporation ("Company"), each other Person that has delivered a Joinder Agreement pursuant to Section 7.13 from time to time party hereto (together with Company, individually or collectively, as the context may require, "Borrower"), the several banks and other financial institutions or entities from time to time party hereto (each, a "Lender", and collectively "Lenders") and HERCULES CAPITAL, INC., a Maryland corporation, in its capacity as administrative agent and collateral agent for itself and Lenders (in such capacity, including any successors or assigns, "Agent").

RECITALS

A. Borrower has requested Lenders make available to Borrower up to five (5) tranches of term loans in an aggregate principal amount of up to Two Hundred Seventy-Five Million Dollars ($275,000,000) (the "Term Loans"); and

B. Lenders are willing to make the Term Loans on the terms and conditions set forth in this Agreement.

AGREEMENT

NOW, THEREFORE, Borrower, Agent and Lenders agree as follows:

SECTION 1. DEFINITIONS AND RULES OF CONSTRUCTION

1.1 Unless otherwise defined herein, the following capitalized terms shall have the following meanings:

"Account Control Agreement(s)" means any agreement entered into by and among Agent, Borrower and a third-party bank or other institution (including a Securities Intermediary) in which Borrower maintains a Deposit Account or an account holding Investment Property and which perfects Agent's first priority security interest in the subject account or accounts.

"ACH Authorization" means the ACH Debit Authorization Agreement in substantially the form of Exhibit H, which account numbers shall be redacted for security purposes if and when filed publicly by Borrower.

"Acquired Indebtedness" means, with respect to any specified Person, Indebtedness (other than indebtedness for borrowed money) of any other Person existing at the time such other Person is merged, consolidated or amalgamated with or into or became a Subsidiary of such specified Person and not incurred in connection with, or in contemplation of, such other Person merging, amalgamating or consolidating with or into, or becoming a Subsidiary of, such specified Person.

"Acquisition" means any transaction or series of related transactions for the purpose of or resulting, directly or indirectly, in (a) the acquisition of all or substantially all of the assets of a Person, or of any business, line of business or division or other unit of operation of a Person, (b) the acquisition of fifty percent (50%) or more of the Equity Interests of any Person, whether or not involving a merger, consolidation or similar transaction with such other Person, or otherwise causing any Person to become a Subsidiary of Borrower, or (c) the acquisition of, or the right to use, develop or sell (in each case, including

through licensing (other than "off-the-shelf" licenses or non-exclusive licenses that are granted in connection with services, vendor or similar contracts where the grant of intellectual property rights is ancillary to the services to be rendered or products to be provided under such contract), any product, product line or intellectual property of or from any other Person.

"Acquisition Deferred Payments" means, with respect to an Acquisition, any "earnouts," holdbacks, performance based-milestones, royalties, purchase price adjustments, profit sharing arrangements, deferred purchase money amounts, indemnifications, non-competition agreements, incentive payments, and other similar payment obligations, and other contingent obligations and agreements consisting of the adjustment of purchase price or similar adjustments.

"Advance(s)" means a Term Loan Advance.

"Advance Date" means the funding date of any Advance.

"Advance Request" means a request for an Advance submitted by Borrower to Agent in substantially the form of Exhibit A, which account numbers shall be redacted for security purposes if and when filed publicly by Borrower.

"Affiliate" means (a) any Person that directly or indirectly controls, is controlled by, or is under common control with the Person in question, (b) any Person directly or indirectly owning, controlling or holding with power to vote ten percent (10%) or more of the outstanding voting securities of another Person, (c) any Person ten percent (10%) or more of whose outstanding voting securities are directly or indirectly owned, controlled or held by another Person with power to vote such securities, or (d) any Person related by blood or marriage to any Person described in subsection (a), (b) or (c) of this definition. As used in the definition of "Affiliate," the term "control" means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through ownership of voting securities, by contract or otherwise.

"Agreement" means this Loan and Security Agreement, as amended, restated, amended and restated, supplemented or otherwise modified from time to time.

"Anti-Corruption Laws" means all laws, rules, and regulations of any jurisdiction applicable to Borrower or any of its Affiliates from time to time concerning or relating to bribery or corruption, including without limitation the United States Foreign Corrupt Practices Act of 1977, as amended, the UK Bribery Act 2010 and other similar legislation in any other jurisdictions.

"Anti-Terrorism Laws" means any laws, rules, regulations or orders relating to terrorism or money laundering, including without limitation Executive Order No. 13224 (effective September 24, 2001), the USA PATRIOT Act, the laws comprising or implementing the Bank Secrecy Act, and the laws administered by OFAC.

"Bankruptcy Code" means the federal bankruptcy law of the United States as from time to time in effect, currently as Title 11 of the United States Code. Section references to current sections of the Bankruptcy Code shall refer to comparable sections of any revised version thereof if section numbering is changed.

"Biologics License Application" means an application for licensure of a biological product submitted to the FDA under 42 U.S.C. § 262(k) for permission to introduce, or deliver for introduction, a biologic product into interstate commerce.

"Blocked Person" means any Person: (a) listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (b) owned or controlled by, or acting for or on behalf of, any Person that is listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (c) with which any Lender is prohibited from dealing or otherwise engaging in any transaction by any Anti-Terrorism Law, (d) that commits, threatens or conspires to commit or supports "terrorism" as defined in Executive Order No. 13224, or (e) that is named a "specially designated national" or "blocked person" on the most current list published by OFAC or other similar list.

"Board Approved Forecast" means the Net Product Revenue projections approved by Company's Board of Directors and delivered in accordance with Section 7.1(i), which projections must be acceptable to Agent in its reasonable discretion.

"Board of Directors" means, with respect to any Person that is a corporation, its board of directors, with respect to any Person that is a limited liability company, its board of managers, board of members or similar governing body, and with respect to any other Person that is another form of a legal entity, such Person's governing body in accordance with its Organizational Documents.

"Borrower Products" means all products, software, service offerings, technical data or technology currently being designed, manufactured or sold or that are under clinical investigation or development by Borrower or any of its Subsidiaries or which Borrower or any of its Subsidiaries intends to sell, license, or distribute in the future including any products or service offerings under development, collectively, together with all products, software, service offerings, technical data or technology that have been sold, licensed or distributed by Borrower since its incorporation and remain material to its business.

"Borrower's Books" means Borrower's or any of its Subsidiaries' books and records including ledgers, federal, state, local and foreign tax returns, records regarding Borrower's or its Subsidiaries' assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

"Business Day" means any day other than Saturday, Sunday and any other day on which banking institutions in the State of California are closed for business.

"Cash" means all cash, cash equivalents and liquid funds, in each case, excluding any Digital Assets.

"Change in Control" means (a) at any time, any "person" or "group" (as such terms are used in Sections 13(d) and 14(d) of Securities Exchange Act of 1934, as amended), shall become, or obtain rights (whether by means of warrants, options or otherwise) to become, the "beneficial owner" (as defined in Rules 13(d)-3 and 13(d)-5 under Securities Exchange Act of 1934, as amended), directly or indirectly, of more than fifty percent (50.0%) of the ordinary voting power for the election of directors, partners, managers and members, as applicable, of Company (determined on a fully diluted basis); (b) "change of control", "fundamental change", "make-whole fundamental change" or any comparable term under and as defined in any indenture governing any Permitted Convertible Debt Financing has occurred; (c) [reserved]; or (d) at any time, Company shall cease to own and control, of record and beneficially, directly or indirectly, one hundred percent (100.0%) of each class of outstanding stock, partnership, membership, or other ownership interest or other equity securities of each Subsidiary of Company, except in connection with a joint venture or strategic alliance permitted by Section 7.6 or a transaction permitted by Section 7.9, free and clear of all Liens (other than Permitted Liens).

"Charter" means, with respect to any Person, such Person's incorporation, formation or equivalent documents, as in effect from time to time.

"Closing Date" means the date of this Agreement.

"Code" means the U.S. Internal Revenue Code of 1986, as amended.

"Collateral Claim" means any and all present and future "claims" (used in its broadest sense, as contemplated by and defined in Section 101(5) of the Bankruptcy Code, but without regard to whether such claim would be disallowed under the Bankruptcy Code) of a Lender now or hereafter arising or existing under or relating to this Agreement and related Loan Documents, whether joint, several, or joint and several, whether fixed or indeterminate, due or not yet due, contingent or non-contingent, matured or unmatured, liquidated or unliquidated, or disputed or undisputed, whether under a guaranty or a letter of credit, and whether arising under contract, in tort, by law, or otherwise, any interest or fees thereon (including interest or fees that accrue after the filing of a petition by or against Borrower under the Bankruptcy Code, irrespective of whether allowable under the Bankruptcy Code), any costs of Enforcement Actions, including reasonable attorneys' fees and costs, and any prepayment or termination premiums.

"Common Stock" means the Common Stock, $0.0001 par value per share, of Company.

"Company IP" means any and all of the following, as they exist in and throughout the United States of America: (a) Current Company IP; (b) improvements, continuations, continuations-in-part, divisions, provisionals or any substitute applications, any Patent issued with respect to any of the Current Company IP, any Patent right claiming the composition of matter of, or the method of making or using, the Borrower Products in the United States of America, any reissue, reexamination, renewal or Patent term extension or adjustment (including any supplementary protection certificate) of any such Patent, and any confirmation Patent or registration Patent or patent of addition based on any such Patent; (c) trade secrets or trade secret rights, including any rights to unpatented inventions, know-how, show-how, operating manuals, confidential or proprietary information, research in progress, algorithms, data, databases, data collections, designs, processes, procedures, methods, protocols, materials, formulae, drawings, schematics, blueprints, flow charts, models, strategies, prototypes, techniques, and the results of experimentation and testing, including samples, in each case, as specifically related to any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of the Borrower Products; (d) any and all IP Ancillary Rights specifically relating to any of the foregoing; and (e) regulatory filings, submissions and approvals related to any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of the Products and all data provided in any of the foregoing.

"Compliance Certificate" means a certificate in the form attached hereto as Exhibit E.

"Contingent Obligation" means, as applied to any Person, any direct or indirect liability, contingent or otherwise, of that Person with respect to (i) any Indebtedness of another Person, including any such obligation directly or indirectly guaranteed, endorsed, co-made or discounted or sold with recourse by that Person, or in respect of which that Person is otherwise directly or indirectly liable; (ii) any obligations with respect to undrawn letters of credit, corporate credit cards or merchant services issued for the account of that Person; and (iii) all obligations arising under any interest rate, currency or commodity swap agreement, interest rate cap agreement, interest rate collar agreement, or other agreement or arrangement designed to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; provided, however, that the term "Contingent Obligation" shall not include endorsements for collection or deposit in the ordinary course of business. The amount of any Contingent Obligation shall be deemed, without duplication of the primary obligation, to be an amount equal to the stated or determined amount of the primary obligation in respect of which such Contingent Obligation is made or, if not stated or determinable, the maximum reasonably anticipated liability in respect thereof as determined by such Person in good faith; provided, however, that such amount shall not in any event exceed

the maximum amount of the obligations under the guarantee or other support arrangement. For the avoidance of doubt, no Permitted Bond Hedge Transaction or Permitted Warrant Transaction will be considered a Contingent Obligation of Borrower.

"Copyright License" means any written agreement granting any right to use any Copyright or Copyright registration, now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest.

"Copyrights" means all copyrights, whether registered or unregistered, held pursuant to the laws of the United States of America, any State thereof, or of any other country.

"Default" means any event, circumstance or condition that has occurred or exists, that would, with the passage of time or the requirement that notice be given or both, become an Event of Default.

"Deposit Accounts" means any "deposit accounts", as such term is defined in the UCC, and includes any checking account, savings account, or certificate of deposit.

"Digital Assets" means all cryptocurrencies, virtual currencies, coins, tokens and other digital assets.

"Disqualified Equity Interests" means any Equity Interests that, by their terms (or by the terms of any security or other Equity Interests into which they are convertible or for which they are exchangeable), or upon the happening of any event or condition (a) mature or are mandatorily redeemable (other than solely for Qualified Equity Interests) pursuant to a sinking fund obligation or otherwise (except as a result of a change of control or asset sale so long as any rights of the holders thereof upon the occurrence of a change of control or asset sale event shall be subject to the prior repayment in full of the Secured Obligations (other than Surviving Obligations)), (b) are redeemable at the option (except as a result of a change of control or asset sale so long as any rights of the holders thereof upon the occurrence of a change of control or asset sale event shall be subject to the prior repayment in full of the Secured Obligations (other than Surviving Obligations)) of the holder thereof (other than solely for Qualified Equity Interests), in whole or in part, (c) provide for scheduled payments of dividends in Cash, or (d) are or become convertible into or exchangeable for Indebtedness or any other Equity Interests that would constitute Disqualified Equity Interests, in each case, prior to the date that is one hundred eighty (180) days after the Term Loan Maturity Date; provided that if such Equity Interests are issued pursuant to any plan for the benefit of any employee, officer, director, manager or consultant of a Loan Party, any Subsidiary thereof, or by any such plan to such employee, officer, director, manager or consultant, such Equity Interests shall not constitute Disqualified Equity Interests solely because they may be required to be repurchased by a Loan Party or any Subsidiary thereof in order to satisfy applicable statutory or regulatory obligations or as a result of the termination, death or disability of such employee, officer director, manager or consultant.

"Division" means, in reference to any Person which is an entity, the division of such Person into two (2) or more separate Persons, with the dividing Person either continuing or terminating its existence as part of such division, including, without limitation, as contemplated under Section 18-217 of the Delaware Limited Liability Company Act for limited liability companies formed under Delaware law, Section 17-220 of the Delaware Revised Uniform Limited Partnership Act for limited partnerships formed under Delaware law, or any analogous action taken pursuant to any other applicable law with respect to any corporation, limited liability company, partnership or other entity.

"Domestic Subsidiary" means any Subsidiary organized under the laws of the United States of America, any State thereof, the District of Columbia, or any other jurisdiction within the United States of America.

"Enforcement Action" means, with respect to any Lender and with respect to any Collateral Claim of such Lender or any item of Collateral in which such Lender has or claims a security interest lien or right of offset, any action, whether judicial or nonjudicial, to repossess, collect, accelerate, offset, recoup, give notification to third parties with respect to, sell, dispose of, foreclose upon, give notice of sale, disposition, or foreclosure with respect to, or obtain equitable or injunctive relief with respect to, such Collateral Claim or Collateral. The filing, or the joining in the filing, by any Lender of an involuntary bankruptcy or Insolvency Proceeding against Borrower also is an Enforcement Action.

"Equity Interests" means, with respect to any Person, the capital stock, partnership or limited liability company interest, or other equity securities or equity ownership interests of such Person.

"ERISA" means the Employee Retirement Income Security Act of 1974, as amended, and the regulations promulgated thereunder.

"Excluded Accounts" means any of the following Deposit Accounts which are designated as such in writing to Agent as of the Closing Date or, with respect to any Deposit Account opened after the Closing Date, in the next Compliance Certificate delivered after such Deposit Account is opened: (a) Deposit Accounts exclusively used for payroll, payroll taxes, and other employee wage and benefit payments to or for the benefit of Borrower's employees holding an aggregate amount across all such accounts of not more than amounts needed for the then-next two (2) payroll cycles, (b) any Deposit Account which is a zero-balance disbursement account, (c) any Deposit Account which is solely used for disbursements and payments of withheld income taxes, payroll taxes and/or federal, state or local employee taxes, (d) any Deposit Account which is solely used as a trust account, escrow account, or other fiduciary account, and (e) accounts used exclusively to maintain cash collateral subject to a Permitted Lien.

"Excluded Subsidiaries" means (a) the MSC Subsidiary, and (b) all Foreign Subsidiaries that (i) generate in the aggregate less than 5.00% of the consolidated trailing twelve month revenue calculated in accordance with GAAP of the Company and its Subsidiaries as of the last day of the most recent fiscal month for which financial statements of the Company are available, (ii) hold in the aggregate assets that constitute less than 5.00% of consolidated total assets of the Company and its Subsidiaries, at any time, (iii) hold in the aggregate Cash less than of One Million Dollars ($1,000,000) at any time, and (iv) holds no Intellectual Property; provided that, notwithstanding the foregoing, an Excluded Subsidiary may license Intellectual Property on a non-exclusive basis or own de minimis Intellectual Property such as Trademarks protecting its name or logo; provided further that, if the aforementioned thresholds are exceeded at any time, then Borrower shall designate in writing to the Agent one or more of such Foreign Subsidiaries to become a Borrower to the extent necessary to eliminate such excess.

"FDA" means the U.S. Food and Drug Administration or any successor thereto.

"FDA Laws" means all applicable guidelines, policies and Requirements of Law administered, implemented, enforced or issued by FDA or any comparable governmental authority.

"First Amendment Closing Date" means December 8, 2025.

"Foreign Subsidiary" means a Subsidiary other than any Domestic Subsidiary.

"Funding Account" means the deposit account maintained by [**], bearing account number [**] in which Borrower has an interest (which, for the avoidance of doubt, shall be the account into which the proceeds of the Loan will be funded into on the Closing Date).

"GAAP" means generally accepted accounting principles in the United States of America, as in effect from time to time.

"Governmental Approval" means any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

"Governmental Authority" means any federal, state, municipal, national or other government, governmental department, commission, board, bureau, court, agency or instrumentality or political subdivision thereof (including the FDA) or any entity or officer exercising executive, legislative, judicial, regulatory or administrative functions of or pertaining to any government or any court, in each case whether associated with a state or locality of the United States, the United States, or a foreign government.

"Guarantor" means any Subsidiary of Borrower that enters into a Guaranty.

"Guaranty" means a guaranty with respect to the Secured Obligations, in form and substance satisfactory to Agent that may be entered into from time to time, as the same may from time to time be amended, restated, modified or otherwise supplemented.

"Hedge Agreement" means any interest rate, currency or commodity swap agreement, interest rate cap agreement, interest rate collar agreement, fuel or mineral or other commodity hedge or exchange agreement or any other agreement or arrangement entered into for non-speculative purposes designated to protect a Person against fluctuation in interest rates currency exchange rates, commodity or mineral prices other than in connection with a Permitted Bond Hedge Transaction or Permitted Warrant Transaction.

"Indebtedness" means indebtedness of any kind, including (a) all indebtedness for borrowed money or the deferred purchase price of property or services (excluding trade credit entered into in the ordinary course of business due within ninety (90) days), including reimbursement and other obligations with respect to surety bonds and letters of credit, (b) all obligations evidenced by notes, bonds, debentures or similar instruments, (c) all capital lease obligations, (d) all obligations to purchase, redeem, retire or defease Disqualified Equity Interests, (e) "earnouts", purchase price adjustments, profit sharing arrangements, deferred purchase money amounts and similar payment obligations or continuing obligations of any nature arising out of purchase and sale contracts but only in each case of the foregoing as and to the extent of the amount required to be reflected as a liability on the balance sheet of such Person in accordance with GAAP, (f) [reserved], (g) non-contingent obligations to reimburse any bank or Person in respect of amounts paid under a letter of credit, banker's acceptance or similar instrument, and (h) all Contingent Obligations. For the avoidance of doubt, no Permitted Bond Hedge Transaction or Permitted Warrant Transaction will be considered Indebtedness of Borrower.

"Insolvency Proceeding" means any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy, liquidation, moratorium, receivership, or insolvency law, including assignments for the benefit of creditors, compositions, extensions generally with its creditors, or proceedings seeking reorganization, administration, arrangement, receivership or other similar relief proceedings in the applicable jurisdiction from time to time in effect and affecting the rights of creditors generally.

"Intellectual Property" means all of Borrower's Copyrights; Trademarks; Patents; Licenses; trade secrets and inventions; mask works; Borrower's applications therefor and reissues, extensions, or renewals thereof; and Borrower's goodwill associated with any of the foregoing, together

with Borrower's rights to sue for past, present and future infringement of Intellectual Property and the goodwill associated therewith.

"Intellectual Property Security Agreement" means the Intellectual Property Security Agreement dated as of the Closing Date between Loan Parties and Agent, as the same may from time to time be amended, restated, modified or otherwise supplemented.

"Investment" means (a) any beneficial ownership (including stock, shares, partnership interests, limited liability company interests, or other equity securities or ownership interests) of or in any Person, (b) any loan, advance or capital contribution to any Person, (c) any Acquisition, or (d) other transfers on behalf of or in connection with any equity ownership or similar transfers.

"IP Ancillary Rights" means, with respect to any Copyright, Trademark, Patent, software, trade secrets or trade secret rights, including any rights to unpatented inventions, know-how, show-how and operating manuals, all income, royalties, proceeds and liabilities at any time due or payable or asserted under or with respect to any of the foregoing or otherwise with respect thereto, including all rights to sue or recover at law or in equity for any past, present or future infringement, misappropriation, dilution, violation or other impairment thereof, and, in each case, all rights to obtain any other intellectual property right ancillary to any Copyright, Trademark, Patent, software, trade secrets or trade secret rights.

"IRS" means the U.S. Internal Revenue Service.

"Joinder Agreements" means for each Subsidiary required to join as a Borrower or as a Guarantor pursuant to Section 7.13, a completed and executed Joinder Agreement in substantially the form attached hereto as Exhibit F.

"License" means any Copyright License, Patent License, Trademark License or other Intellectual Property license of rights or interests.

"Lien" means any mortgage, deed of trust, pledge, hypothecation, assignment for security, security interest, encumbrance, levy, lien or charge of any kind, whether voluntarily incurred or arising by operation of law or otherwise, against any property, any conditional sale or other title retention agreement, and any lease in the nature of a security interest.

"Loan" means the Advances made under this Agreement.

"Loan Documents" means this Agreement, the promissory notes (if any), the ACH Authorization, the Account Control Agreements, any Joinder Agreement, all UCC Financing Statements, any Guaranty, the Pledge Agreement, the Intellectual Property Security Agreement, and any other documents executed in connection with the Secured Obligations or the transactions contemplated hereby, as the same may from time to time be amended, modified, supplemented or restated.

"Loan Party" means Borrower or any Guarantor.

"Market Capitalization" means, for any given date of determination, an amount equal to (a) the average of the daily volume weighted average price of Company's common Equity Interests as reported for each of the five (5) Trading Days preceding such date of determination *multiplied by* (b) the total number of issued and outstanding shares of Company's common Equity Interests that are issued and outstanding on the date of the determination and listed on the Principal Stock Exchange, subject to appropriate adjustment for any stock dividend, stock split, stock combination, reclassification or other similar transaction during the applicable calculation period.

"Market Disruption Event" means any of the following events: (a) any suspension of, or limitation imposed on, trading by the Principal Stock Exchange in shares of common Equity Interests during any period or periods aggregating one hour or longer and whether by reason of movements in price exceeding limits permitted by the Principal Stock Exchange or otherwise relating to the common Equity Interests; or (b) the failure to open of the exchange or quotation system on which the common Equity Interests are traded or the closure of such exchange or quotation system prior to its respective scheduled closing time for the regular trading session on such day (without regard to after hours or other trading outside the regular trading session hours).

"Material Adverse Effect" means a material adverse effect upon: (i) the business, operations, properties, assets or financial condition of the Loan Parties and their respective Subsidiaries taken as a whole; or (ii) the ability of Borrower to perform or pay the Secured Obligations in accordance with the terms of the Loan Documents, or the ability of Agent or Lenders to enforce any of its rights or remedies with respect to the Secured Obligations; or (iii) the Collateral or Agent's Liens on the Collateral or the priority of such Liens.

"Material Agreement" means any license, agreement or other contractual arrangement the termination of which before the end of its stated term could be reasonably expected to result in a Material Adverse Effect individually or in the aggregate.

"Material Regulatory Liabilities" means (a) (i) any liabilities arising from the violation of applicable laws, rules or regulations (including FDA Laws), or necessary to remedy any violation of any terms or conditions applicable to any Registrations), including, but not limited to, withdrawal of approval, recall, revocation, suspension, import detention and seizure of any Borrower Product, and (ii) any loss of recurring annual revenues as a result of any loss, suspension or limitation of any Registrations, which, in the case of the foregoing clauses (i) and (ii), could reasonably be expected to result in a Material Adverse Effect.

"Milestone" means, individually and collectively, Data Milestone ~~1~~I, Data Milestone ~~2~~II, Approval Milestone 1, Approval Milestone 2, Commercial Milestone and Financing Milestone.

"MSC Investment Conditions" means that Borrower maintains Qualified Cash in an amount equal to or greater than the lesser of (i) one hundred percent (100%) of the aggregate outstanding Secured Obligations (inclusive of any Prepayment Charge and End of Term Charge that would be due and owing if the outstanding Loans were prepaid at the time of measurement) or (ii) one hundred percent (100%) of the consolidated Cash of Borrower and its Subsidiaries (other than Cash held in an Excluded Account), unless compliance with the foregoing conditions are waived in writing from time to time by Agent (in its sole discretion) with respect to specified periods.

"MSC Subsidiary" means Dyne Therapeutics Securities Corporation, a wholly-owned Subsidiary incorporated in the Commonwealth of Massachusetts for the purpose of holding Investments as a Massachusetts security corporation under 830 CMR 63.38B.1 of the Massachusetts tax code and applicable regulations (as the same may be amended, modified or replaced from time to time).

"Net Product Revenue" means Borrower's net product revenue (as determined in accordance with GAAP) solely from the sale of DYNE-101 and DYNE-251, which shall not include any royalty, profit sharing, sales-based milestone revenue, upfront or non-sales-based milestone payments under business development or licensing transactions, measured on as of the date of the most recently delivered monthly or quarterly financial statements in accordance with Section 7.1(a) or Section 7.1(b). For the avoidance of doubt, net product revenue shall not include any of the following to the extent not recognizable as revenue in accordance with GAAP: (i) trade, quantity and cash discounts allowed by

Borrower, (ii) discounts, refunds, rebates, charge backs, retroactive price adjustment and any other allowances which effectively reduce net selling price, (iii) product returns and allowances, (iv) allowances for shipping or other distribution expenses, (v) set-offs and counterclaims, and (vi) any other similar and customary deductions that are typically deducted from gross revenue and not included in net revenue in accordance with GAAP.

"Non-Disclosure Agreement" means that certain Confidentiality Agreement by and between Company and Agent dated as of [**].

"OFAC" means the U.S. Department of Treasury Office of Foreign Assets Control.

"OFAC Lists" means, collectively, the Specially Designated Nationals and Blocked Persons List maintained by OFAC pursuant to Executive Order No. 13224, 66 Fed. Reg. 49079 (Sept. 25, 2001) and/or any other list of terrorists or other restricted Persons maintained pursuant to any of the rules and regulations of OFAC or pursuant to any other applicable Executive Orders.

"Organizational Documents" means with respect to any Person, such Person's Charter, and (a) if such Person is a corporation, its bylaws, (b) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (c) if such Person is a partnership, its partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto.

"Paid in Full", "Pay in Full" or "Payment in Full" shall mean the indefeasible payment in full in cash of all Secured Obligations other than inchoate indemnification obligations which, by their terms, survive termination of this Agreement (such obligations, "Surviving Obligations") and Lenders have no further commitment or obligation hereunder or under any other Loan Documents to make any further Advances.

"Patent License" means any written agreement granting any right with respect to any invention on which a Patent is in existence or a Patent application is pending, in which agreement Borrower now holds or hereafter acquires any interest.

"Patents" means all letters patent of, or rights corresponding thereto, in the United States of America or in any other country, all registrations and recordings thereof, and all applications for letters patent of, or rights corresponding thereto, in the United States of America or any other country.

"Perfection Certificate" means a completed certificate entitled "Perfection Certificate", dated as of the Closing Date, delivered by Company to Agent and Lenders, signed by Company (as amended or supplemented pursuant to the terms of this Agreement).

"Permitted Acquisition" means any Acquisition which is conducted in accordance with the following requirements:

(i) of a business or Person or product engaged in a line of business related to that of Borrower or its Subsidiaries;

(ii) if such Acquisition is structured as a stock acquisition, then the Person so acquired shall (a) be domiciled in the United States of America, and (b) either (1) become a wholly-owned Subsidiary of Borrower or of a Subsidiary and Borrower shall comply, or cause such Subsidiary to comply, with Section 7.13 or (2) such Person shall be merged with and into Borrower (with Borrower being the surviving entity);

(iii) if such Acquisition is structured as the acquisition or in-licensing of assets, the assets acquired in the case of an acquisition (or, in the case of in-licensing, the rights to use such assets in accordance with the license agreement) shall be (a) except for de-minimis assets or any assets acquired in an in-licensing transaction, located entirely in the United States of America, (b) acquired by Borrower or a newly-organized wholly-owned Subsidiary (in which event such Subsidiary shall comply with Section 7.13 hereof), and (c) free and clear of Liens other than Permitted Liens;

(iv) Borrower shall have delivered to Lenders not less than fifteen (15) (or such shorter period as Agent may agree) nor more than forty five (45) days prior to the closing date of such Acquisition, (a) notice of such Acquisition together with copies of all material documents relating to such Acquisition, and, (b) in the case of a stock acquisition or the acquisition of a division or line of business, pro forma projected financial information and historical financial statements for such acquired entity, division or line of business (in each case, to the extent applicable), in each case in a form reasonably satisfactory to Lenders and demonstrating compliance with the covenants set forth in Section 7.21 then in effect on a pro forma basis as if the Acquisition occurred on the first day of the most recent measurement period;

(v) both immediately before and after such Acquisition no Default or Event of Default shall have occurred and be continuing; and

(vi) the sum of the purchase price of such proposed new Acquisition, computed on the basis of total acquisition consideration paid or incurred, or to be paid or incurred, by Borrower with respect thereto, including any unpaid Acquisition Deferred Payment that is not required to be reflected as a liability on the balance sheet of Borrower in accordance with GAAP, and including the amount of Permitted Indebtedness assumed or to which such assets, businesses or business or ownership interest or shares, or any Person so acquired, is subject, shall not be greater than (x) until such time as Borrower achieves either Approval Milestone I or the Approval Milestone II (i) [**] Dollars ($[**]) per fiscal year for any single acquisition or group of related acquisitions or (ii) [**] Dollars ($[**]) for all such acquisitions during the term of this Agreement and (y) after Borrower achieves either Approval Milestone I or the Approval Milestone II (i) [**] Dollars ($[**]) per fiscal year for any single acquisition or group of related acquisitions or (ii) [**] Dollars ($[**]) for all such acquisitions during the term of this Agreement; provided that (1) acquisition consideration funded by proceeds from the sale and issuance of Borrower's Qualified Equity Interests in a transaction not resulting in a Change in Control, which sale and issuance has a primary purpose to fund such Acquisition, and which sale and issuance is consummated substantially contemporaneously with (and in any event, prior to, but no more than thirty (30) days prior to) the consummation of such Acquisition, shall be disregarded in determining compliance with this clause (vi); (2) for any Acquisition in which the consideration consists solely of Qualified Equity Interests of Borrower, the value of such Qualified Equity Interests shall be disregarded in determining compliance with this clause (vi).

"Permitted Bond Hedge Transaction" means any call or capped call option (or substantively equivalent derivative transaction) relating to Common Stock (or other securities or property following a merger event or other change of Common Stock) purchased by Borrower in connection with the issuance of any Permitted Convertible Debt Financing.

"Permitted Convertible Debt Financing" means issuance by Company of convertible notes in one or more transactions in an aggregate principal amount of not more than [**] Dollars ($[**]) ("Permitted Convertible Debt"); provided that such convertible notes shall (a) both immediately prior to and immediately after giving effect (including pro forma effect) thereto, no Default or Event of Default

shall exist or result therefrom, (b) have no scheduled amortization or principal payments, mandatory redemptions or other required payments of principal prior to the date that is one hundred eighty (180) days after the Term Loan Maturity Date, other than customary payments upon a "change of control", "fundamental change", "make-whole fundamental change" or any comparable term (it being understood that a holder's option to convert any such Indebtedness into Common Stock (and Cash in lieu of fractional shares) shall not be considered a required mandatory redemption or payment of principal and payments of interest shall be permitted), (c) be unsecured or secured, (d) not be guaranteed by any Subsidiary of Company that is not a Borrower or a guarantor of the Secured Obligations, (e) if secured, contain usual and customary subordination terms for underwritten offerings of senior subordinated convertible notes, (f) shall be Indebtedness of Company and not of any Subsidiary thereof, and (g) if secured, shall specifically designate this Agreement and all Secured Obligations as "designated senior indebtedness" or similar term so that the subordination terms referred to in clause (e) of this definition specifically refer to such notes as being subordinated to the Secured Obligations pursuant to such subordination terms. For the avoidance of doubt, Permitted Convertible Debt Financing shall not constitute Subordinated Indebtedness.

"Permitted Indebtedness" means:

(i) Indebtedness of Borrower in favor of any Lender or Agent arising under this Agreement or any other Loan Document;

(ii) Indebtedness existing on the Closing Date which is disclosed in Schedule 1A;

(iii) Indebtedness of up to [**] Dollars ($[**]) outstanding at any time secured by a Lien described in clause (vii) of the defined term "Permitted Liens," provided such Indebtedness does not exceed the cost of the Equipment, software or other Intellectual Property financed with such Indebtedness plus customary fees, expenses and taxes;

(iv) Indebtedness to trade creditors incurred in the ordinary course of business (other than trade credit that is past due by more than one hundred twenty (120) days), including such Indebtedness incurred in the ordinary course of business with corporate credit cards in an aggregate outstanding amount not to exceed [**] Dollars ($[**]) at any time;

(v) Indebtedness that also constitutes a Permitted Investment or is secured by a Permitted Lien;

(vi) Subordinated Indebtedness;

(vii) reimbursement obligations in connection with letters of credit or Hedge Agreements (entered into in order to manage existing or anticipated interest rate, exchange rate or commodity price risks and not for speculative purposes), that are at any time outstanding and secured by Cash and issued on behalf of Borrower or a Subsidiary in an amount not to exceed [**] Dollars ($[**]);

(viii) other unsecured Indebtedness in an amount not to exceed [**] Dollars ($[**]) at any time outstanding;

(ix) intercompany Indebtedness of (A) any Loan Party owing to another Loan Party, or (B) any Foreign Subsidiary that is an Excluded Subsidiary resulting from a Permitted Investment in accordance with clause (x) of the defined term "Permitted Investments";

(x) the Permitted Convertible Debt Financing;

(xi) Indebtedness with respect to a Permitted Royalty Transaction;

(xii) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of business;

(xiii) Indebtedness consisting of financing of insurance premiums in the ordinary course of business;

(xiv) Indebtedness in respect of netting services, overdraft protection and similar arrangements in connection with deposit or securities accounts in the ordinary course of business;

(xv) Indebtedness consisting of guarantees with respect to surety and appeal bonds, performance bonds, bid bonds, appeal bonds, completion guarantees, and similar obligations up to an aggregate amount of [**] Dollars ($[**]) at any one time outstanding;

(xvi) Acquired Indebtedness not to exceed [**] Dollars ($[**]) outstanding;

(xvii) Indebtedness in respect of Acquisition Deferred Payments incurred in connection with Permitted Acquisitions;

(xviii) the Thermo Fisher Installment Payments, subject to the terms and conditions of Section 7.25 of this Agreement; and

(xix) ~~(xviii)~~ extensions, refinancings and renewals of any items of Permitted Indebtedness, provided that the principal amount is not increased or the terms modified to impose materially more burdensome (taken as a whole) terms upon Borrower or its Subsidiary, as the case may be.

"Permitted Investment" means:

(i) Investments existing on the Closing Date which are disclosed in Schedule 1B;

(ii) (a) marketable direct obligations issued or unconditionally guaranteed by the United States of America or any agency or any State thereof maturing within one year from the date of acquisition thereof currently having a rating of at least A-2 or P-2 from either Standard & Poor's Corporation or Moody's Investors Service, (b) commercial paper maturing no more than one year from the date of creation thereof and currently having a rating of at least A-2 or P-2 from either Standard & Poor's Corporation or Moody's Investors Service, (c) certificates of deposit maturing no more than one year from the date of investment therein, which are either (x) issued by any bank with assets of at least Five Hundred Million Dollars ($500,000,000), or (y) are fully FDIC-insured, (d) money market accounts, and (e) Investments permitted by Borrower's investment policy as provided to Agent and Lenders prior to the Closing Date, as amended from time to time; provided that any material amendments thereto have been approved in writing by Agent and the Lenders in their reasonable discretion;

(iii) repurchases of stock of Borrower from former employees, directors, or consultants of Borrower under the terms of applicable repurchase agreements at the original issuance price of such securities in an aggregate amount not to exceed [**] Dollars ($[**]) in any fiscal year, provided that no Event of Default has occurred, is continuing or would exist after giving effect to the repurchases;

(iv) Investments accepted in connection with Permitted Transfers;

(v) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of Borrower's business;

(vi) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business, provided that this subsection (vi) shall not apply to Investments of any Loan Party in any Subsidiary of a Loan Party;

(vii) Investments consisting of loans not involving the net transfer on a substantially contemporaneous basis of cash proceeds to employees, officers or directors relating to the purchase of capital stock of Company pursuant to employee stock purchase plans or other similar agreements approved by Company's Board of Directors;

(viii) Investments consisting of: (A) travel advances and employee relocation loans in the ordinary course of business, and (B) loans to employees, officers, managers or directors relating to the purchase of equity securities of Borrower pursuant to employee stock purchase plans or agreements approved by Borrower's Board of Directors or similar governing body; not to exceed [**] Dollars ($[**]) in the aggregate for (A) and (B), collectively, from the Closing Date until Payment in Full;

(ix) Investments in newly-formed Subsidiaries, provided that each such Subsidiary has complied with Section 7.13;

(x) Investments in Foreign Subsidiaries that are Excluded Subsidiaries (including newly-formed Foreign Subsidiaries) not to exceed [**] Dollars ($[**]) in the aggregate in any fiscal year, and other amounts approved in advance in writing by Agent;

(xi) Investments in the MSC Subsidiary, so long as an Event of Default does not exist at the time of such Investment and would not exist after giving effect to such Investment and provided that Borrower is, before and after giving effect to such Investment, in compliance with the MSC Investment Conditions;

(xii) joint ventures or strategic alliances in the ordinary course of Borrower's business consisting of the nonexclusive licensing of technology, the development of technology or the providing of technical support, provided that any cash Investments by Borrower do not exceed [**] Dollars ($[**]) in the aggregate in any fiscal year; and provided, further, that, for the avoidance of doubt, any cost-sharing arrangements in connection with collaborative studies with third parties shall not be subject to any such limitation;

(xiii) Investments constituting Permitted Acquisitions;

(xiv) Investments consisting of Deposit Accounts and securities accounts permitted by this Agreement; and

(xv) additional Investments that do not exceed [**] Dollars ($[**]) in the aggregate.

"Permitted Liens" means:

(i) Liens in favor of Agent or Lenders;

(ii) Liens existing on the Closing Date which are disclosed in Schedule 1C;

(iii) Liens for taxes, fees, assessments or other governmental charges or levies, either not yet due or being contested in good faith by appropriate proceedings diligently conducted; provided, that Borrower maintains adequate reserves therefor on Borrower's Books in accordance with GAAP;

(iv) Liens securing claims or demands of materialmen, artisans, mechanics, carriers, warehousemen, landlords and other like Persons arising in the ordinary course of Borrower's business and imposed without action of such parties; provided, that the payment thereof is not yet required;

(v) Liens arising from judgments, decrees or attachments in circumstances which do not constitute an Event of Default hereunder;

(vi) the following deposits, to the extent made in the ordinary course of business: deposits under worker's compensation, unemployment insurance, social security and other similar laws, or to secure the performance of bids, tenders or contracts (other than for the repayment of borrowed money) or to secure indemnity, performance or other similar bonds for the performance of bids, tenders or contracts (other than for the repayment of borrowed money) or to secure statutory obligations (other than Liens arising under ERISA or environmental Liens) or surety or appeal bonds, or to secure indemnity, performance or other similar bonds;

(vii) Liens on Equipment or software or other intellectual property constituting purchase money Liens and other Liens in connection with capital leases securing Indebtedness permitted in clause (iii) of "Permitted Indebtedness";

(viii) Liens incurred in connection with Subordinated Indebtedness;

(ix) leasehold interests in leases or subleases and licenses (other than with respect to Intellectual Property) granted in the ordinary course of business and not interfering in any material respect with the business of the licensor;

(x) Liens in favor of customs and revenue authorities arising as a matter of law to secure payment of custom duties that are promptly paid on or before the date they become due;

(xi) Liens on insurance proceeds securing the payment of financed insurance premiums that are promptly paid on or before the date they become due (provided that such Liens extend only to such insurance proceeds and not to any other property or assets);

(xii) statutory and common law rights of set-off and other similar rights as to deposits of cash and securities in favor of banks, other depository institutions and brokerage firms;

(xiii) easements, servitudes, zoning restrictions, rights-of-way and similar encumbrances on real property imposed by law or arising in the ordinary course of business so long as they do not materially impair the value or marketability of the related property;

(xiv) (a) Liens on Cash securing obligations permitted under clause (vii) of the definition of Permitted Indebtedness and (b) security deposits in connection with real property leases, the combination of (a) and (b) in an aggregate amount not to exceed [**] Dollars ($[**]) at any time;

(xv) Licenses that qualify as Permitted Transfers;

(xvi) Liens in connection with a Permitted Royalty Transaction consisting of (i) Liens or back-up Liens solely on the royalty interest purchased pursuant to a true sale Permitted Royalty Transaction and the proceeds thereof, and segregated accounts into which such purchased royalty interests (and only such royalty interests) are paid (such account, a "Permitted Segregated Royalty Account"), or (ii) Liens on Company IP that comply with clause (b) of the definition of Permitted Royalty Transaction;

(xvii) Liens solely on any Cash earnest money deposits made by Borrower or any of its Subsidiaries in connection with any letter of intent or purchase agreement that constitutes a Permitted Acquisition in an aggregate amount not to exceed [**] percent ([**]%) of the aggregate purchase consideration paid in connection thereto; and

(xviii) Liens incurred in connection with the extension, renewal or refinancing of the Indebtedness secured by Permitted Liens; provided, that any extension, renewal or replacement Lien shall be limited to the property encumbered by the existing Lien and the principal amount of the Indebtedness being extended, renewed or refinanced (as may have been reduced by any payment thereon) does not increase.

"Permitted Out-Licenses" means licenses, sub-licenses and similar arrangements for the use of the Intellectual Property entered into on arms' length basis, that could not result in a legal transfer of title of the licensed property and which may be exclusive in respects other than territory, and with respect to territory shall be either: (a) non-exclusive; (b) exclusive but only as to discrete geographical areas outside of the United States of America; (c) exclusive as to specific geographic regions or territories including the United States but only as it relates to assets other than DYNE-101 and DYNE-251 for the Duchenne muscular dystrophy or myotonic dystrophy type 1 indications; provided, that, with respect to this clause (c), the same is for a specific disease indication and/or a specific drug target such that it does not limit the use of the Borrower's technology platform in a manner that would prevent Borrower from continuing to develop DYNE-101 and DYNE-251 in the United States or being able to further develop and transact its technology platform. Agent shall, if reasonably requested by Borrower, enter into customary non-disturbance agreements, in form and substance reasonably acceptable to Agent, in connection with the entry by Borrower or any Subsidiary into any out-license that constitutes a Permitted Out-License.

"Permitted Transfers" means:

(i) sales of Inventory in the ordinary course of business;

(ii) Permitted Out-Licenses;

(iii) transfers by and among Borrower and any Subsidiary that has executed a Joinder Agreement;

(iv) transfers constituting the making of Permitted Investments, or the granting of Permitted Liens;

(v) dispositions of worn-out, obsolete or surplus Equipment at fair market value in the ordinary course of business; and

(vi) Transfers consisting of royalty payments in connection with any Permitted Royalty Transaction;

(vii) use of Cash in the ordinary course of business to the extent not prohibited pursuant to the terms of the Loan Documents;

(viii) the sale of Qualified Equity Interests to the extent not causing a Change in Control;

(ix) the abandonment, cancellation, allowing to lapse, or other disposition of any Patents, Trademarks or Copyrights that are no longer used or useful to the Loan Parties or, subject to Agent's approval, which shall not be unreasonably withheld or delayed, are no longer economically practicable to maintain; *provided* that absence of receipt of Agent's approval by Borrower within 5 Business Days following Borrower providing notice of such decision shall be deemed to be Agent's approval; and *provided, further*, that Agent's approval shall not be required in relation to routine decisions concerning ex-US and national stage filing strategies occurring in the normal course of prosecution or for any abandonment, cancellation, allowance to lapse, or other disposition that does not result in a complete loss of rights in relation to the Patents, Trademarks, or Copyrights (such as abandoning a patent application in favor of a continuation or divisional application);

(x) subleases of real property or the termination of real property leases in the ordinary course of business;

(xi) transactions permitted under Section 7.9; and

(xii) other Transfers of assets having a fair market value of not more than [**] Dollars ($[**]) in the aggregate in any fiscal year.

"Permitted Royalty Transaction" means either a true royalty or synthetic royalty financing whereby Borrower receives or has rights to receive unencumbered and unrestricted (including, not subject to any redemption, clawback, escrow or similar encumbrance or restriction, but excluding encumbrances and restrictions under the Loan Documents) net cash proceeds of no less than [**] Dollars ($[**]) (or, if a lesser percentage of revenue is sold, no less than a pro-rated amount based on such lesser percentage) in exchange for rights to receive future payments based on net sales, revenue or milestones, as applicable, of DYNE-101 and/or DYNE-251 in an amount not to exceed, in the aggregate for all such Permitted Royalty Transactions, [**] percent ([**]%) (or, if a lesser amount of cash proceeds is to be received, no less than a pro-rated percentage based on such lesser amount) of worldwide net sales or revenue, as applicable, of DYNE-101 and/or DYNE-251; provided that such transaction (a) in the case of any synthetic royalty financings (and not royalty purchases or buyouts) with respect to DYNE-101 and/or DYNE-251, shall be subject to an intercreditor agreement in form and substance satisfactory to Agent in its sole discretion, (b) for which any security is granted, shall have such grant of security limited solely to DYNE-101 and/or DYNE-251 and such security is subordinated to Agent's first priority Lien, and (c) shall not have a guaranteed minimum return payment or "true-up" payment earlier than one hundred eighty (180) days after the Term Loan Maturity Date and/or subject to Payment in Full and if structured as Indebtedness, shall not have a scheduled maturity date earlier than one hundred eighty (180) days after the Term Loan Maturity Date; provided further that Borrower shall not engage in more than one such transaction, for each of DYNE-101 and DYNE-251, at any one time. For the avoidance of doubt, the aforementioned figures shall be

scalable (e.g. an amount not less than [**] Dollars ($[**]) for each transaction in exchange for a promise to pay future royalties on net sales of not more than [**]% of total DYNE-101 and/or [**]% of total DYNE-251 net product revenue). Agent shall, if requested by Borrower, release its Lien on purchased revenue streams in connection with a "true sale" of an existing revenue stream that (i) constitutes a Permitted Royalty Transaction, and (ii) is not a synthetic royalty transaction as determined by the Agent in its reasonable business judgment.

"Permitted Warrant Transaction" means any call option, warrant or right to purchase (or substantively equivalent derivative transaction) relating to Common Stock (or other securities or property following a merger event or other change of the Common Stock) and/or cash (in an amount determined by reference to the price of such Common Stock) sold by Borrower in connection with any Permitted Convertible Debt Financing and substantially concurrently with any purchase by Borrower of a related Permitted Bond Hedge Transaction and as may be amended in accordance with its terms; provided that (x) that the terms, conditions and covenants of each such call option transaction are customary for agreements of such type, as determined in good faith by the board of directors of Borrower or a committee thereof and (y) such call option transaction would be classified as an equity instrument in accordance with GAAP.

"Person" means any individual, sole proprietorship, partnership, joint venture, trust, unincorporated organization, association, corporation, limited liability company, institution, other entity or government.

"Pledge Agreement" means the Pledge Agreement dated as of the Closing Date between Borrower and Agent, as the same may from time to time be amended, restated, modified or otherwise supplemented.

"Principal Stock Exchange" means the NASDAQ or, if the common Equity Interests are not listed on the NASDAQ, the principal national securities exchange or public quotation system on which the common Equity Interests are then listed for trading or quoted.

"Qualified Cash" means an amount equal to (a) the amount of Borrower's Cash held in accounts subject to an Account Control Agreement in favor of Agent *minus* (b) the aggregate amount of all outstanding Indebtedness or any other amounts owed by Borrower pursuant to the Thermo Fisher Agreement.

"Qualified Equity Interests" means any Equity Interests that are not Disqualified Equity Interests.

"Qualified Equity Issuance Net Proceeds" means the cumulative net proceeds in Cash (excluding any conversion of existing notes, share repurchases, or other holdbacks or discounts) received by Company as consideration for any (a) public or private sale or issuance of any Qualified Equity Interests of Company, (b) contribution to the equity capital of Company (other than in exchange for Disqualified Equity Interests), (c) sale or issuance of Indebtedness of Company (other than intercompany Indebtedness) that may be converted into or exchanged for Qualified Equity Interests of Company and which constitutes a Permitted Convertible Debt Financing, (d) Permitted Royalty Transaction, (e) sale or issuance of Subordinated Indebtedness, or (f) entry into a Permitted Out-License; provided that the amount of Cash received by Company is, (i) in the case of clauses (a) and (b) above, measured at the time made and without adjustment for subsequent changes in value, payable for the fair market value of sale, issuance or contribution and any other property received in connection with such sale, issuance or contribution, and paid by any Person that is not a Loan Party or an Affiliate thereof, and (ii) in the case of clause (c) above, the aggregate principal amount of Indebtedness sold or issued.

"Receivables" means (i) all of Borrower's Accounts, Instruments, Documents, Chattel Paper, Supporting Obligations, letters of credit, proceeds of any letter of credit, and Letter of Credit Rights, and (ii) all customer lists, software, and business records related thereto.

"Redemption Conditions" means, with respect to any cash payment in connection with a redemption or prepayment of any Permitted Convertible Debt, satisfaction of each of the following events: (a) no Default or Event of Default shall exist or result therefrom, and (b) both immediately before and after such redemption, the Borrower's Qualified Cash shall be no less than [**] percent ([**]%) of the Secured Obligations (inclusive of any Prepayment Charge and End of Term Charge that would be due and owing if the outstanding Term Loan Advances were prepaid at the time of measurement).

"Registration" means any registration, authorization, approval, license, permit, clearance, certificate, and exemption issued or allowed by the FDA or state pharmacy licensing authorities (including, without limitation, new drug applications, Biologics License Applications, abbreviated new drug applications, investigational new drug applications, pricing and reimbursement approvals, labelling approvals or their foreign equivalent, and wholesale distributor permits).

"Required Lenders" means at any time, the holders of more than fifty percent (50%) of the sum of the aggregate unpaid principal amount of the Term Loans then outstanding. "Sanctioned Country" means, at any time, a country or territory which is the subject or target of any Sanctions.

"Sanctioned Person" means, at any time, (a) any Person listed in any Sanctions-related list of designated Persons maintained by the Office of Foreign Assets Control of the U.S. Department of the Treasury or the U.S. Department of State, or by the United Nations Security Council, the European Union or any EU member state, (b) any Person operating, organized or resident in a Sanctioned Country or (c) any Person controlled by any such Person.

"Sanctions" means economic or financial sanctions or trade embargoes imposed, administered or enforced from time to time by (a) the U.S. government, including those administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury or the U.S. Department of State, or (b) the United Nations Security Council, the European Union or His Majesty's Treasury of the United Kingdom.

"SBA Funding Date" means each date on which a Lender which is an SBIC funds any portion of the Term Loans.

"Secured Obligations" means Borrower's obligations under this Agreement and any Loan Document, including any obligation to pay any amount now owing or later arising.

"Subordinated Indebtedness" means Indebtedness subordinated to the Secured Obligations in amounts and on terms and conditions reasonably satisfactory to Agent and subject to a subordination agreement in form and substance satisfactory to Agent in its sole discretion.

"Subsidiary" means an entity, whether a corporation, partnership, limited liability company, joint venture or otherwise, in which Borrower owns or controls, either directly or indirectly, fifty percent (50%) or more of the outstanding voting securities, including each entity listed on Schedule 1.

"Taxes" means all present or future taxes, levies, imposts, duties, deductions, withholdings (including backup withholding), assessments, fees or other charges imposed by any Governmental Authority, including any interest, additions to tax or penalties applicable thereto.

"Term Loan" means any Term Loan Advance made under this Agreement.

"Term Loan Advance" means each Tranche 1 Advance, Tranche 2 Advance, Tranche 3 Advance, Tranche 4 Advance, Tranche 5 Advance and any other funds advanced under Section 2.2(a).

"Thermo Fisher Agreement" means each Extended Payment Schedule Agreement entered into by and between Borrower and Thermo Fisher Financial Services, Inc., a Delaware corporation, which agreement shall be in a form reasonably satisfactory to Agent; provided that Agent and Lenders understand and agree that Borrower may enter into an Extended Payment Schedule Agreement on up to a monthly basis without Agent approval at any time after Agent provides its initial approval, in writing, of the form of Extended Payment Schedule Agreement, so long as the form used is identical in all respects to the initially approved form. For the avoidance of doubt, any change to the initially approved form of Extended Payment Schedule Agreement shall require Agent's prior written approval.

"Thermo Fisher Installment Payments" means those certain installment payments made by Borrower pursuant to any Thermo Fisher Agreement when due and payable under the terms of such Thermo Fisher Agreement; provided that the maximum aggregate unpaid amount of such installment payments shall not at any time exceed Thirty-Five Million Dollars ($35,000,000).

"Trademark License" means any written agreement granting any right to use any Trademark or Trademark registration, now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest.

"Trademarks" means all trademarks (registered, common law or otherwise) and any applications in connection therewith, including registrations, recordings and applications in the United States Patent and Trademark Office or in any similar office or agency of the United States of America, any State thereof or any other country or any political subdivision thereof.

"Trading Day" means any day on which (a) there is no Market Disruption Event and (b) the Principal Stock Exchange is open for trading; provided that a "Trading Day" only includes those days that have a scheduled closing time of 4:00 p.m. (Eastern time) or the then standard closing time for regular trading on the relevant exchange or trading system.

"Tranche" means the Tranche 1 Advance, Tranche 2 Advance, Tranche 3 Advance, Tranche 4 Advance and/or Tranche 5 Advance, as applicable.

"U.S. Person" means any Person that is a "United States person" as defined in Section 7701(a)(30) of the Code.

"UCC" means the Uniform Commercial Code as the same is, from time to time, in effect in the State of New York; provided, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection or priority of, or remedies with respect to, Agent's Lien on any Collateral is governed by the Uniform Commercial Code as the same is, from time to time, in effect in a jurisdiction other than the State of New York, then the term "UCC" shall mean the Uniform Commercial Code as in effect, from time to time, in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority or remedies and for purposes of definitions related to such provisions.

1.2 The following terms are defined in the Sections or subsections referenced opposite such terms:

Defined Term	Section

1940 Act	5.6(b)
Act	8.1
Agent	Preamble
Amortization Date	Exhibit K
Approval Milestone I	Exhibit K
Approval Milestone II	Exhibit K
Assignee	11.14
At-the-Market Offering	Exhibit K
Borrower	Preamble
Claims	11.11(a)
Collateral	3.1
Commercial Milestone	Exhibit K
Company	Preamble
Confidential Information	11.13
Current Company IP	5.10(a)
Data Milestone I	Exhibit K
Data Milestone II	Exhibit K
Due Diligence Fee	Exhibit K
End of Term Charge	Exhibit K
End of Term Charge Percentage	Exhibit K
Event of Default	9
Excluded Assets	3.2
Financial Statements	7.1
Financing Milestone	Exhibit K
First Interest Only Extension Conditions	Exhibit K
Indemnified Person	6.3
Information	5.7
Initial Facility Charge	Exhibit K
Initial Minimum Cash Test Date	Exhibit K
Initial Minimum Revenue Test Date	Exhibit K
Initial Revenue Trigger Test Date	Exhibit K
Lenders	Preamble
Liabilities	6.3
Maximum Rate	2.3
Maximum Term Loan Amount	Exhibit K
Minimum Advance Amount	Exhibit K
Participant Register	11.8
Payment Date	2.2(e)

Permitted Convertible Debt Financing Payments	7.24
Permitted Segregated Royalty Account	Clause (xvi) of the definition of "Permitted Liens"
Prepayment Charge	Exhibit K
Prime Rate	Exhibit K
Publicity Materials	11.19
Register	11.7
Second Interest Only Extension Conditions	Exhibit K
Subsequent Financing	Exhibit K
Subsequent Tranche Facility Charge	Exhibit K
Surviving Obligations	Definition of "Payment in Full"
Term Commitment	Exhibit K
Term Loan Interest Rate	Exhibit K
Term Loan Maturity Date	Exhibit K
Tranche 1 Advance	2.2(a)
Tranche 1 Commitment	Exhibit K
Tranche 2 ~~Advances~~Advance	2.2(a)
Tranche 2 Commitment	Exhibit K
~~**Tranche 2 Commitment Period**~~	~~Exhibit K~~
Tranche 2 Milestone	Exhibit K
Tranche 3 Advances	2.2(a)
Tranche 3 Commitment	Exhibit K
Tranche 3 Commitment Period	Exhibit K
Tranche 3 Milestone	Exhibit K
Tranche 4 Advances	2.2(a)
Tranche 4 Commitment	Exhibit K
Tranche 4 Commitment Period	Exhibit K
Tranche 4 Milestone	Exhibit K
Tranche 5 Commitment	Exhibit K
Tranche 5 Commitment Period	Exhibit K
Transfer	7.8

1.3 Unless otherwise specified, all references in this Agreement or any Annex or Schedule hereto to a "Section," "subsection," "Exhibit," "Annex," or "Schedule" shall refer to the corresponding Section, subsection, Exhibit, Annex, or Schedule in or to this Agreement. Unless otherwise specifically provided herein, any accounting term used in this Agreement or the other Loan Documents shall have the meaning customarily given such term in accordance with GAAP as in effect on the date hereof, and all

financial computations hereunder shall be computed in accordance with GAAP as in effect on the date hereof, consistently applied. Unless otherwise defined herein or in the other Loan Documents, terms that are used herein or in the other Loan Documents and defined in the UCC shall have the meanings given to them in the UCC. For all purposes under the Loan Documents, in connection with any Division or plan of Division under Delaware law (or any comparable event under a different jurisdiction's laws): (a) if any asset, right, obligation or liability of any Person becomes the asset, right, obligation or liability of a different Person, then it shall be deemed to have been transferred from the original Person to the subsequent Person and (b) if any new Person comes into existence, such new Person shall be deemed to have been organized on the first date of its existence by the holders of its Equity Interests at such time.

1.4 If at any time any change in GAAP would affect the computation of any financial requirement set forth in any Loan Document, and either Borrower or the Required Lenders shall so request, Agent, Lenders and Borrower shall negotiate in good faith to amend such requirement to preserve the original intent thereof in light of such change in GAAP; provided that, until so amended, such requirement shall continue to be computed in accordance with GAAP prior to such change.

1.5 Any reference in any Loan Document to a merger, transfer, consolidation, amalgamation, consolidation, assignment, sale, disposition or transfer, or similar term, shall be deemed to apply to a Division of or by a limited liability company, or an allocation of assets to a series of a limited liability company (or the unwinding of such a Division or allocation), as if it were a merger, transfer, consolidation, amalgamation, consolidation, assignment, sale or transfer, or similar term, as applicable, to, of or with a separate Person. Any Division of a limited liability company shall constitute a separate Person under the Loan Documents (and each Division of any limited liability company that is a Subsidiary, joint venture or any other like term shall also constitute such a Person or entity) on the first date of its existence. In connection with any Division, if any asset, right, obligation or liability of any Person becomes the asset, right, obligation or liability of a different Person, then such asset shall be deemed to have been transferred from the original Person to the subsequent Person.

1.6 Notwithstanding anything in the definition of GAAP to the contrary, any obligations under a lease that is not (or would not be) a capital lease under GAAP as in effect prior to giving effect to FASB Accounting Standards Update No. 2016-02, Leases, shall not be treated as a capital lease solely as a result of the adoption of changes in GAAP.

SECTION 2. THE LOAN

2.1 [Reserved]

2.2 Term Loan Advances.

(a) Advances.

(i) Tranche 1. Subject to the terms and conditions of this Agreement, on the Closing Date, Lenders shall severally (and not jointly) make, and Borrower agrees to draw, a Term Loan Advance in an aggregate principal amount equal to the Tranche 1 Commitment (such Term Loan Advance, the "Tranche 1 Advance").

(ii) Tranche 2. Subject to the terms and conditions of this Agreement~~, Borrower may request, and the~~ and Borrower's achievement of Data Milestone I, on the First Amendment Closing Date, Lenders shall severally (and not jointly) make, ~~in each case, at any time during the Tranche 2 Commitment Period, up to three additional Term Loan Advances in minimum increments of the Minimum Advance Amount (or if less, the~~

~~remaining amount of Term Loan Advances available to be drawn pursuant to this Section 2.2(a)(ii))~~and Borrower agrees to draw, a Term Loan Advance in an aggregate principal amount ~~up~~equal to the Tranche 2 Commitment (such Term Loan ~~Advances~~Advance, the "Tranche 2 ~~Advances~~Advance").

(iii) Tranche 3. Subject to the terms and conditions of this Agreement, Borrower may request, and the Lenders shall severally (and not jointly) make, in each case, at any time during the Tranche 3 Commitment Period, up to three additional Term Loan Advances in minimum increments of the Minimum Advance Amount (or if less, the remaining amount of Term Loan Advances available to be drawn pursuant to this Section 2.2(a)(iii)) in an aggregate principal amount up to the Tranche 3 Commitment (such Term Loan Advances, the "Tranche 3 Advances").

(iv) Tranche 4. Subject to the terms and conditions of this Agreement, Borrower may request, and the Lenders shall severally (and not jointly) make, in each case, at any time during the Tranche 4 Commitment Period, up to three additional Term Loan Advances in minimum increments of the Minimum Advance Amount (or if less, the remaining amount of Term Loan Advances available to be drawn pursuant to this Section 2.2(a)(iv)) in an aggregate principal amount up to the Tranche 4 Commitment (such Term Loan Advances, the "Tranche 4 Advances").

(v) Tranche 5. Subject to the terms and conditions of this Agreement, Borrower may request, and the Lenders shall severally (and not jointly) make, in each case, at any time during the Tranche 5 Commitment Period, and conditioned on approval by Lenders' investment committee in its sole and unfettered discretion, one or more additional Term Loan Advances in minimum increments of the Minimum Advance Amount (or if less, the remaining amount of Term Loan Advances available to be drawn pursuant to this Section 2.2(a)(v)) in an aggregate principal amount up to the Tranche 5 Commitment (such Term Loan Advances, the "Tranche 5 Advances").

(b) Maximum Term Loan Amount. The aggregate outstanding Term Loan Advances shall not exceed the Maximum Term Loan Amount. Each Term Loan Advance of each Lender shall not exceed its respective Term Commitment. After repayment, no Term Loan Advance (or any portion thereof) may be reborrowed.

(c) Advance Request. To obtain a Term Loan Advance, Borrower shall complete, sign and deliver an Advance Request (at least one (1) Business Day before the Closing Date and at least five (5) Business Days before each Advance Date other than the Closing Date) to Agent. Lenders shall fund the Term Loan Advance in the manner requested by the Advance Request provided that each of the conditions precedent set forth in Section 4 and applicable to such Term Loan Advance is satisfied as of the requested Advance Date. The proceeds of any Term Loan Advance shall be deposited into an account that is subject to an Account Control Agreement.

(d) Interest.

(i) Term Loan Interest Rate. The principal balance shall bear interest thereon from such Advance Date at the Term Loan Interest Rate, based on a year consisting of three hundred sixty (360) days, with interest computed daily based on the actual number of days elapsed. The Term Loan Interest Rate will float and change on the day the Prime Rate changes from time to time.

(e) Payment. Borrower will pay accrued but unpaid interest on each Term Loan Advance on the first Business Day of each month (each such date, a "Payment Date"), beginning the month after the Advance Date. Borrower shall repay the aggregate principal balance of the Term Loan Advances that is outstanding on the day immediately preceding the Amortization Date, in equal monthly installments of principal and interest (mortgage style) beginning on the Amortization Date and continuing on the first Business Day of each month thereafter until Payment in Full. The entire principal balance of the Term Loan Advances and all accrued but unpaid interest hereunder, shall be due and payable on the Term Loan Maturity Date; provided, that if the Term Loan Maturity Date is not a Business Day, the Term Loan Maturity Date shall be the immediately subsequent Business Day. Borrower shall make all payments under this Agreement without setoff, recoupment or deduction and regardless of any counterclaim or defense, other than Taxes, which shall be governed by Addendum 1. If a payment hereunder becomes due and payable on a day that is not a Business Day, the due date thereof shall be the immediately subsequent Business Day. Agent or Lenders will initiate debit entries to Borrower's account as authorized on the ACH Authorization (i) on each Payment Date of all periodic obligations payable to Lenders under each Term Loan Advance outstanding and (ii) reasonable and documented out-of-pocket legal fees and costs incurred by Agent or Lenders that is reimbursable by Borrower in accordance with Section 11.12; provided that, with respect to clause (i) above, in the event that Lenders or Agent informs Borrower that Lenders will not initiate a debit entry to Borrower's account for a certain amount of the periodic obligations due on a specific Payment Date, Borrower shall pay to Lenders, such amount of periodic obligations in full in immediately available funds on such Payment Date; provided, further, that, with respect to clause (i) above, if Lenders or Agent informs Borrower that Lenders will not initiate a debit entry as described above later than the date that is three (3) Business Days prior to such Payment Date, Borrower shall pay to Lenders such amount of periodic obligations in full in immediately available funds on the date that is three (3) Business Days after the date on which Lenders or Agent notifies Borrower of such; provided, further, that, with respect to clause (ii) above, in the event that Lenders or Agent informs Borrower that Lenders will not initiate a debit entry to Borrower's account for specified reasonable and documented out-of-pocket legal fees and costs incurred by Agent or Lenders, Borrower shall pay to Lenders such amount in full in immediately available funds within three (3) Business Days after the date on which Lenders or Agent notifies Borrower of such.

2.3 Maximum Interest. Notwithstanding any provision in this Agreement or any other Loan Document to the contrary, it is the parties' intent not to contract for, charge or receive interest at a rate that is greater than the maximum rate permissible by law that a court of competent jurisdiction shall deem applicable hereto (which under the laws of the State of New York shall be deemed to be the laws relating to permissible rates of interest on commercial loans) (the "Maximum Rate"). If a court of competent jurisdiction shall finally determine that Borrower has actually paid to Lenders an amount of interest in excess of the amount that would have been payable if all of the Secured Obligations had at all times borne interest at the Maximum Rate, then such excess interest actually paid by Borrower shall be applied as follows: first, to the payment of the Secured Obligations consisting of the outstanding principal; second, after all principal is repaid, to the payment of Lenders' accrued interest, costs, expenses, professional fees and any other Secured Obligations then due and payable hereunder; and third, after all Secured Obligations are repaid (other than inchoate indemnity obligations), the excess (if any) shall be refunded to Borrower.

2.4 Default Interest. In the event any payment is not paid on the scheduled payment date, an amount equal to four percent (4%) of such past due amount shall be payable on demand. In addition, upon the occurrence and during the continuation of an Event of Default hereunder, all outstanding Secured Obligations, including principal, interest, compounded interest, and professional fees, shall bear interest at a rate per annum equal to the rate set forth in Section 2.2(d)

plus four percent (4%) per annum. In the event any interest is not paid when due hereunder, delinquent interest shall be added to principal and shall bear interest on interest, compounded at the rate set forth in Section 2.2(d) or 2.4, as applicable.

2.5 Prepayment. At its option, Borrower may prepay all or a portion of the outstanding Advances by paying the entire principal balance (or such portion thereof) all accrued and unpaid interest thereon, all unpaid Lender's fees and expenses then due and payable hereunder accrued to the date of the repayment (including, without limitation, the portion of the End of Term Charge applicable to the aggregate original principal amount of the Term Loan Advances being prepaid in accordance with Section 2.6(a)), together with a Prepayment Charge with respect to the outstanding principal amount of such Advance amount being so prepaid. Borrower agrees that the Prepayment Charge is a reasonable calculation of Lenders' lost profits in view of the difficulties and impracticality of determining actual damages resulting from an early repayment of the Advances. Borrower shall prepay the outstanding amount of all principal and accrued interest through the prepayment date and the Prepayment Charge upon the occurrence of a Change in Control or any other prepayment hereunder. Notwithstanding the foregoing, Agent and Lenders agree to waive the Prepayment Charge if Agent and Lenders (in their sole and absolute discretion) agree in writing to refinance the Advances prior to the Term Loan Maturity Date. Any amounts paid under this Section shall be applied by Agent to the then unpaid amount of any outstanding Secured Obligations (including principal and interest) in such order and priority as Agent may choose in its sole discretion. For the avoidance of doubt, if a payment hereunder becomes due and payable on a day that is not a Business Day, the due date thereof shall be the immediately subsequent Business Day.

2.6 End of Term Charge.

(a) On any date that Borrower partially prepays the outstanding Secured Obligations pursuant to Section 2.5, Borrower shall pay Lenders a charge equal to the product of the End of Term Charge Percentage *multiplied* by the principal amount of such Term Loan Advances being prepaid.

(b) On the earliest to occur of (i) the Term Loan Maturity Date, (ii) Payment in Full or (iii) the date that the outstanding Secured Obligations become due and payable, Borrower shall pay Lenders a charge equal to the End of Term Charge.

(c) Notwithstanding the required payment date of such End of Term Charge, the applicable pro rata portion of the End of Term Charge shall be deemed earned by Lenders as of each date that an applicable Term Loan Advance is made. For the avoidance of doubt, if a payment hereunder becomes due and payable on a day that is not a Business Day, the due date thereof shall be the immediately subsequent Business Day.

2.7 Pro Rata Treatment. Each payment (including prepayment) on account of any fee and any reduction of the Term Loan Advances shall be made pro rata according to the Term Commitments of the relevant Lender.

2.8 Taxes; Increased Costs. Borrower, Agent and Lenders each hereby agree to the terms and conditions set forth on Addendum 1 attached hereto.

2.9 Treatment of Prepayment Charge and End of Term Charge. Borrower agrees that any Prepayment Charge and any End of Term Charge payable shall be presumed to be the liquidated damages sustained by each Lender as the result of the early termination, and Borrower agrees that it is reasonable under the circumstances currently existing and existing as of the Closing Date. The

Prepayment Charge and the End of Term Charge shall also be payable in the event the Secured Obligations (and/or this Agreement) are satisfied or released by foreclosure (whether by power of judicial proceeding), deed in lieu of foreclosure, or by any other means. Each Loan Party expressly waives (to the fullest extent it may lawfully do so) the provisions of any present or future statute or law that prohibits or may prohibit the collection of the foregoing Prepayment Charge and End of Term Charge in connection with any such acceleration. Borrower agrees (to the fullest extent that each may lawfully do so): (a) each of the Prepayment Charge and the End of Term Charge is reasonable and is the product of an arm's length transaction between sophisticated business people, ably represented by counsel; (b) each of the Prepayment Charge and the End of Term Charge shall be payable notwithstanding the then prevailing market rates at the time payment is made; (c) there has been a course of conduct between Lenders and Borrower giving specific consideration in this transaction for such agreement to pay the Prepayment Charge and the End of Term Charge as a charge (and not interest) in the event of prepayment or acceleration; and (d) Borrower shall be estopped from claiming differently than as agreed to in this Section. Borrower expressly acknowledges that its agreement to pay each of the Prepayment Charge and the End of Term Charge to Lenders as herein described was on the Closing Date and continues to be a material inducement to Lenders to provide the Term Loan Advances.

2.10 Due Diligence Fee. Borrower agrees that the Due Diligence Fee has been paid to Agent and received by Agent prior to the Closing Date, and shall be deemed fully earned on such date regardless of the early termination of this Agreement. The Agent agrees that the Due Diligence Fee shall be applied in its entirety on the Closing Date to towards the Lenders' non-legal transaction costs and diligence expenses.

SECTION 3. SECURITY INTEREST

3.1 Grant of Security Interest. As security for the prompt and complete payment when due (whether on the payment dates or otherwise) of all the Secured Obligations, each Borrower grants to Agent a security interest in all of such Borrower's right, title, and interest in, to and under all of such Borrower's personal property and other assets including without limitation the following (except as set forth herein) whether now owned or hereafter acquired (collectively, excluding the Excluded Assets, the "Collateral"): (a) Receivables; (b) Equipment; (c) Fixtures; (d) General Intangibles; (e) Inventory; (f) Investment Property; (g) Deposit Accounts; (h) Cash; (i) Goods; and all other tangible and intangible personal property of such Borrower whether now or hereafter owned or existing, leased, consigned by or to, or acquired by, Borrower and wherever located, and any of such Borrower's property in the possession or under the control of Agent; and, to the extent not otherwise included, all Proceeds of each of the foregoing and all accessions to, substitutions and replacements for, and rents, profits and products of each of the foregoing.

3.2 Notwithstanding the broad grant of the security interest set forth in Section 3.1, above, the Collateral shall not include (a) any "intent to use" trademarks at all times prior to the first use thereof, whether by the actual use thereof in commerce, the recording of a statement of use with the United States Patent and Trademark Office or otherwise, provided, that upon submission and acceptance by the United States Patent and Trademark Office of an amendment to allege use of an intent-to-use trademark application pursuant to 15 U.S.C. Section 1060(a) (or any successor provision) such intent-to-use application shall constitute Collateral, (b) nonassignable licenses or contracts, which by their terms require the consent of the licensor thereof or another party (but only to the extent such prohibition on transfer is enforceable under applicable law, including, without limitation, Sections 9-406, 9-407 and 9-408 of the UCC), (c) any Excluded Account, (d) any assets as to which Agent in its reasonable discretion shall determine that the costs and burdens of obtaining or perfecting a security interest therein substantially outweigh the benefit to the Lenders of the

security afforded thereby (including, without limitation, vehicles and other assets subject to a certificate of title), (e) more than 65% of the issued and outstanding shares of capital stock which entitle the holder thereof to vote for directors or any other matter of any Foreign Subsidiary, which is an Excluded Subsidiary, formed after the Closing Date, solely to the extent Borrower has provided Agent with evidence satisfactory to Agent that the pledge of more than 65% of such voting stock of such Subsidiary could reasonably be expected to result in a material adverse tax consequence to Borrower, and solely for as long as such consequence may result, such portion of such voting stock of such Subsidiary, if excluded from the Collateral, would avoid such material adverse tax consequence (it being understood that in the case of any Foreign Subsidiary whose ownership does not satisfy the holding period requirement set forth in Section 246(c)(5) of the Code, not more than 65% of such Foreign Subsidiary's stock shall be required to be pledged until the holding period is satisfied), (f) property for which the granting of a security interest therein is contrary to applicable law, rule or regulation, provided that upon the cessation of any such restriction or prohibition, such property shall automatically be included in the Collateral, (g) any cash collateral deposit subject to a Permitted Lien hereunder, provided that upon the termination and release of such cash collateral, such property shall automatically be included in the Collateral, (h) any lease, license or other agreement and any property subject thereto on the Closing Date or on the date of the acquisition of such property (other than any property acquired by a Loan Party subject to any such contract or other agreement to the extent such contract or other agreement was incurred in contemplation of such acquisition) to the extent that a grant of a security interest therein to secure the Secured Obligations would violate or invalidate such lease, license, contract or agreement or create a right of termination in favor of any other party thereto (other than Borrower, any other Loan Party or any Subsidiary) (but (A) only to the extent such prohibition is enforceable under applicable law and (B) other than to the extent that any such term would be rendered ineffective pursuant to Sections 9-406, 9-408 or 9-409 (or any other Section) of Article 9 of the UCC), (i) Equipment or software or other intellectual property (and the products and proceeds thereof) subject to Permitted Liens of the type described in clause (vii) of the definition of Permitted Liens, but only to the extent and for so long as the agreements under which the equipment is financed prohibit granting a security interest therein to Agent and letter-of-credit rights not constituting supporting obligations of other Collateral and (j) any commercial tort claim (as defined in the UCC that does not exceed One Million Dollars ($1,000,000) (collectively, the "Excluded Assets").

3.3 Notwithstanding any of the foregoing or anything in this Agreement or any other Loan Document to the contrary, no perfection steps shall be required with respect to any Excluded Assets.

3.4 Upon Payment in Full, all security interest in the Collateral granted under this Agreement shall immediately terminate and all rights on the Collateral shall revert to Borrower with the need for any other action by any Person. Agent shall execute such documents and take such other steps as are reasonably necessary for Borrower to accomplish the foregoing, all at Borrower's sole cost and expense.

SECTION 4. CONDITIONS PRECEDENT TO LOAN

The obligations of Lenders to make the Loan hereunder are subject to the satisfaction by Borrower (or waiver by the Lenders) of the following conditions:

4.1 Initial Advance. On or prior to the Closing Date, Borrower shall have delivered to Agent the following:

(a) duly executed copies of the Loan Documents to be entered into on the Closing Date, and all other documents and instruments reasonably required by Agent to be delivered on or prior to the Closing Date to effectuate the transactions contemplated hereby or to create and perfect the Liens of Agent with respect to all Collateral, in all cases in form and substance reasonably acceptable to Agent;

(b) duly executed Account Control Agreement with respect to the Funding Account;

(c) a legal opinion of Borrower's counsel in form and substance reasonably acceptable to Agent;

(d) copy of resolutions of each Borrower's Board of Directors, certified by an officer of such Borrower, (i) evidencing approval of the Loan and other transactions evidenced by the Loan Documents, (ii) authorizing a specified person or persons to execute the Loan Documents to which it is a party on its behalf, (iii) authorizing a specified person or persons, on its behalf, to sign and/or dispatch all documents and notices (including, if relevant, any Advance Request or other relevant notice) to be signed and/or dispatched by it under or in connection with the Loan Documents to which it is a party, and (iv) acknowledging that the Board of Directors are acting for a proper purpose and that the Loan Documents are in the best interests of that Borrower and for its commercial benefit;

(e) certified copies of the Charter of Borrower, certified by the Secretary of State of the applicable jurisdiction of organization and the other Organizational Documents, as amended through the Closing Date, of Borrower;

(f) a certificate of good standing for Borrower from its jurisdiction of organization and similar certificates from all other jurisdictions in which it does business and where the failure to be qualified could have a Material Adverse Effect;

(g) certified copies, dated as of a recent date, of searches for financing statements filed in the central filing office of the State of Delaware, accompanied by written evidence (including any UCC termination statements) that the Liens on any Collateral indicated in any such financing statements either constitute Permitted Liens or have been or, in connection with the initial Term Loan Advance, will be terminated or released;

(h) payment of the Due Diligence Fee, Initial Facility Charge and reimbursement of Agent's and Lenders' current expenses reimbursable pursuant to this Agreement, which amounts may be deducted from the initial Advance;

(i) a duly executed copy of the Perfection Certificate and each exhibit and addendum thereto;

(j) subject to Section 6.2, all certificates of insurance required hereunder;

(k) [reserved];

(l) all reports, declarations and forms required by the SBA, including but not limited to SBA 652, SBA 1031 and SBA 480; and

(m) such other documents as Agent may reasonably request.

4.2 All Advances. On each Advance Date:

(a) Agent shall have received (i) an Advance Request for the relevant Advance as required by Section 2.2(c), duly executed by Borrower's Chief Executive Officer or Chief Financial Officer, and (ii) any other documents Agent may reasonably request in its good faith business discretion so long as such request does not result in the intentional delay or denial of the relevant Advance;

(b) The representations and warranties set forth in this Agreement shall be true and correct in all material respects on and as of the applicable Advance Date with the same effect as though made on and as of such date, except to the extent such representations and warranties expressly relate to an earlier date;

(c) [reserved];

(d) With respect to any Advance (other than the Tranche 1 Advance) made available on such Advance Date, the Loan Parties shall have paid, or shall concurrently with such Advance pay, the Subsequent Tranche Facility Charge (which amount may be deducted from such Tranche) applicable to such Advance; and

(e) Each Advance Request shall be deemed to constitute a representation and warranty by Borrower on the relevant Advance Date as to the matters specified in Section 4.2(b) and Section 4.4 and as to the matters set forth in the Advance Request.

4.3 [Reserved.]

4.4 No Default. As of the Closing Date and at the time of and immediately after each Advance Date, (i) no Default or Event of Default shall have occurred and be continuing and (ii) no event that has had or could reasonably be expected to have a Material Adverse Effect has occurred and is continuing.

4.5 Post-Closing Conditions Subsequent. Borrower shall satisfy each of the conditions subsequent to the Closing Date specified in this Section 4.5 to the satisfaction of Agent, in each case, by no later than the date specified for such condition below (or such later date as Agent shall agree in its sole discretion):

(a) Within thirty (30) days of the Closing Date (or such longer period of time as agreed to by Agent in writing in its sole discretion), use commercially reasonable efforts to deliver to the Agent duly executed landlord consents for its (i) chief executive office or its principal place of business and (ii) offices or business locations, including warehouses, containing in excess of Two Million Dollars ($2,000,000) of Borrower's assets or property (other than offices, business locations or warehouses holding primarily (i) works-in-progress, raw materials or otherwise in the supply chain for commercial manufacturing or sale of Borrower Products, (ii) inventory or other goods in transit, or (iii) assets (other than equipment) in connection with clinical and pre-clinical studies, including contract manufacturing organizations, distribution service firms, contract research organizations, clinical sites, clinical investigators and other institutions);

(b) Within thirty (30) days of the Closing Date (or such longer period of time as agreed to by Agent in writing in its sole discretion), use commercially reasonable efforts to deliver to the Agent duly executed bailee agreements for any bailee location holding a portion of Borrower's assets or property valued, individually or in the aggregate, in excess of Three Million Dollars

($3,000,000) (other than bailees or other third parties in possession of: (i) works-in-progress, raw materials or otherwise in the supply chain for commercial manufacturing or sale of Borrower Products, (ii) inventory or other goods in transit, or (iii) assets (other than equipment) in connection with clinical and pre-clinical studies, including contract manufacturing organizations, distribution service firms, contract research organizations, clinical sites, clinical investigators and other institutions);

(c) Within three (3) days of the Closing Date (or such longer period of time as agreed to by Agent in writing in its sole discretion), deliver to Agent duly executed Account Control Agreement(s) with respect to each Deposit Account and account holding Investment Property (other than the Funding Account and any Excluded Account) maintained by Borrower or any Subsidiary (other than the MSC Subsidiary);

(d) Within thirty (30) days of the Closing Date (or such longer period of time as agreed to by Agent in writing in its sole discretion), (i) evidence of cyber liability insurance coverage and (ii) commercial property insurance certificates and endorsements showing Agent as lender's loss payable, as required pursuant to Section 6.2 hereunder; and

(e) Within ten (10) days of the Closing Date (or such longer period of time as agreed to by Agent in writing in its sole discretion), Borrower shall cause the shares of common stock of the MSC Subsidiary and that are the subject of the pledged collateral under the Pledge Agreement to be certificated and the original certificate and power (undated and executed in blank) to be delivered to Agent.

SECTION 5. REPRESENTATIONS AND WARRANTIES OF BORROWER

Borrower represents and warrants that:

5.1 Corporate Status; Execution and Delivery; Binding Effect. Each Borrower is a corporation duly organized, legally existing and in good standing under the laws of its jurisdiction of incorporation, and is duly qualified as a foreign corporation, limited liability company or partnership, as the case may be, in all jurisdictions in which the nature of its business or location of its properties require such qualifications and where the failure to be qualified could reasonably be expected to have a Material Adverse Effect. Borrower's present name, former names (if any), locations, place of formation, tax identification number, organizational identification number and other information are correctly set forth in Exhibit B, as may be updated by Borrower in a written notice (including any Compliance Certificate) provided to Agent after the Closing Date in accordance with this Agreement. This Agreement has been, and each other Loan Document, when delivered hereunder, will have been, duly executed and delivered by the Borrower. This Agreement constitutes, and each other Loan Document when so delivered will constitute, a legal, valid and binding obligation of the Borrower, enforceable against the Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, receivership, moratorium or other laws affecting creditors' rights generally and by general principles of equity.

5.2 Collateral. Borrower owns or otherwise has the rights to use the Collateral, free of all Liens, except for Permitted Liens. Borrower has the power and authority to grant to Agent a Lien in the Collateral as security for the Secured Obligations.

5.3 Consents. Borrower's execution, delivery and performance of this Agreement and all other Loan Documents to which it is a party, (i) have been duly authorized by all necessary action of Borrower in accordance with its Organizational Documents and applicable law, (ii) will not result in the creation or imposition of any Lien upon the Collateral, other than Permitted Liens, (iii) do not violate any provisions of (A) Borrower's Organizational Documents or (B) any material law, regulation, order, injunction, judgment, decree or writ to which Borrower is subject in any material respect and (iv) except as described on Schedule 5.3, do not violate any Material Agreement or require the consent or approval of any other Person or Governmental Authority which has not already been obtained. The individual or individuals executing the Loan Documents are duly authorized to do so.

5.4 Material Adverse Effect. No event that has had or could reasonably be expected to have a Material Adverse Effect has occurred and is continuing. Borrower is not aware of any event or circumstance that is likely to occur that is reasonably expected to result in a Material Adverse Effect; provided that the occurrence of the following, individually, shall not, in and of itself, constitute a "Material Adverse Effect" hereunder: (i) the failure to achieve any Milestone, (ii) adverse results or delays with respect to, or the failure to achieve, any clinical or non-clinical trial goals or objectives, (iii) the denial, delay or limitation or qualification of approval of the FDA or other regulatory agency with respect to any proposed drug or other Borrower Products, or (iv) any revisions to or termination of a strategic alliance, joint venture, co-promotion, co-commercialization or co-development agreements or license arrangement maintained by Borrower so long as the same does not affect the ability of Borrower to perform or pay the Secured Obligations in accordance with the terms of the Loan Documents.

5.5 Actions Before Governmental Authorities. There are no actions, suits, claims, disputes or proceedings at law or in equity or by or before any Governmental Authority now pending or, to the knowledge of Borrower, threatened in writing against or affecting Borrower or its property, that is reasonably expected to result in a Material Adverse Effect.

5.6 Laws.

(a) Neither Borrower nor any of its Subsidiaries is in violation of any law, rule or regulation, or in default with respect to any judgment, writ, injunction or decree of any Governmental Authority to which Borrower or such Subsidiaries are subject, where such violation or default could reasonably be expected to result in a Material Adverse Effect. Borrower is not in default in any material respect under any provision of any agreement or instrument evidencing material Indebtedness or any other Material Agreement to which it is a party or by which it is bound.

(b) Neither Borrower nor any of its Subsidiaries is an "investment company," a company that would be an "investment company" except for the exclusion from the definition of "investment company" in Section 3(c) of the Investment Company Act of 1940, as amended (the "1940 Act"), or a company "controlled" by an "investment company" under the 1940 Act. Neither Borrower nor any of its Subsidiaries is engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Borrower and each of its Subsidiaries has complied in all material respects with the Federal Fair Labor Standards Act. Neither Borrower nor any of its Subsidiaries is a "holding company" or an "affiliate" of a "holding company" or a "subsidiary company" of a "holding company" as each term is defined and used in the Public Utility Holding Company Act of 2005. Neither Borrower's nor any of its Subsidiaries' properties or assets have been used by Borrower or such Subsidiary or, to Borrower's knowledge, by previous Persons, in disposing, producing, storing, treating, or

transporting any hazardous substance other than in material compliance with applicable laws. Borrower and each of its Subsidiaries has obtained all material consents, approvals and authorizations of, made all material declarations or filings with, and given all material notices to, all Governmental Authorities that are necessary to continue in all material respects their respective businesses as currently conducted.

(c) None of Borrower, any of its Subsidiaries, nor (to the knowledge of any Loan Party) any of Borrower's or its Subsidiaries' Affiliates or any of their respective agents acting in connection with the transactions contemplated by this Agreement is (i) in violation of any Anti-Terrorism Law, (ii) engaging in or conspiring to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding or attempts to violate, any of the prohibitions set forth in any Anti-Terrorism Law, or (iii) is a Blocked Person. None of Borrower, any of its Subsidiaries, or (to the knowledge of Borrower) any of their Affiliates or agents acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement, (x) conducts any business or engages in making or receiving any contribution of funds, goods or services to or for the benefit of any Blocked Person, or (y) deals in, or otherwise engages in any transaction relating to, any property or interest in property blocked pursuant to Executive Order No. 13224, any similar executive order or other Anti-Terrorism Law. None of the funds to be provided under this Agreement will be used, directly or indirectly, (a) for any activities in violation of any applicable anti-money laundering, economic sanctions and anti-bribery laws and regulations or (b) for any payment to any governmental official or employee, political party, official of a political party, candidate for political office, or anyone else acting in an official capacity, in order to obtain, retain or direct business or obtain any improper advantage, in violation of the United States Foreign Corrupt Practices Act of 1977, as amended.

5.7 Information Correct and Current. No written information, report, Advance Request, financial statement, exhibit or schedule furnished, by or on behalf of Borrower to Agent in connection with any Loan Document or included therein or delivered pursuant thereto (other than forward looking financial or business projections, or information of a general economic or industry nature) ("Information") contained as of the date such Information was furnished, when taken as a whole with all other Information given or furnished to Agent or any Lender, contains or will contain any material misstatement of fact or, when taken together with all other such information or documents, omitted, omits or will omit to state any material fact necessary to make the statements therein, in the light of the circumstances under which they were, are or will be made, not materially misleading at the time such statement was made or deemed made. Additionally, any and all financial or business projections or forecasts provided by Borrower to Agent under the Loan Documents, whether prior to or after the Closing Date, shall be (i) provided in good faith and based on assumptions believed to be reasonable at the time prepared (it being understood that such projections are subject to significant uncertainties and contingencies, many of which are beyond the control of any Loan Party, that no assurance is given that any particular projections will be realized and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results by a material amount) and (ii) the most current of such projections provided to and approved by Borrower's Board of Directors (other than management updates to years beyond the then-current fiscal year).

5.8 Tax Matters. Except as set forth on Schedule 5.8, (a) Borrower and its Subsidiaries have filed all federal and state income Tax returns and other material Tax returns that they are required to file (taking into account any timely filed extensions), (b) Borrower and its Subsidiaries have duly paid all federal and state income Taxes and other material Taxes or installments thereof that they are required to pay, except Taxes being contested in good faith by appropriate proceedings and for which Borrower and its Subsidiaries maintain adequate reserves in accordance with GAAP

and which Taxes, if not paid would exceed [**] Dollars ($[**]), and (c) to the best of Borrower's knowledge, no proposed or pending Tax assessments, deficiencies, audits or other proceedings with respect to Borrower or any Subsidiary have had, or could reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect.

5.9 Intellectual Property Claims. Borrower is the sole owner of, or otherwise has the right to use, the Current Company IP. Except as described on Schedule 5.9 (as such schedule may be updated by Borrower in a written notice provided from time to time after the Closing Date) or any Compliance Certificate, (i) each of the material Copyrights, Trademarks and Patents is valid and enforceable (other than with respect to expired or pending applications, including Patent applications), (ii) no material part of the Intellectual Property has been judged invalid or unenforceable, in whole or in part, and (iii) except as set forth in the Compliance Certificate delivered for the last month of the most recently ended fiscal quarter in accordance with Section 7.1(d), no claim has been made to Borrower that the ownership of or use of any material part of the Intellectual Property violates the rights of any third party. Exhibit C (which shall be automatically updated after the Closing Date upon Borrower providing the written notices required pursuant to Section 7.22) is a true, correct and complete list of each of Borrower's Patents, registered Trademarks, registered Copyrights, and Material IP Agreements under which Borrower licenses Intellectual Property from third parties (other than shrink-wrap software licenses, "off-the-shelf" licenses, open-source software), together with application or registration numbers, as applicable, owned by Borrower or any Subsidiary. Borrower is not in material breach of, nor has Borrower failed to perform any material obligations under, any of the foregoing contracts, licenses or agreements and, to Borrower's knowledge, no third party to any such contract, license or agreement is in material breach thereof or has failed to perform any material obligations thereunder.

5.10 Intellectual Property.

(a) A true, correct and complete list of each pending, registered or in-licensed Intellectual Property that, individually or taken together with any other such Intellectual Property, is material to the business of Borrower and its Subsidiaries, taken as a whole, relating to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of the Borrower Products, and is owned or co-owned by or exclusively licensed to Borrower or any of its Subsidiaries (collectively, the "Current Company IP"), including its name/title, current owner or co-owners (including ownership interest), registration, patent or application number, and registration or application date, issued or filed in the United States of America, is set forth on Schedule 5.10(a) or in the Compliance Certificate delivered for the last month of the most recently ended fiscal quarter in accordance with Section 7.1(d) (provided that such disclosure made in such Compliance Certificate shall not apply to a period covered by a prior Compliance Certificate and shall not cure any default arising from any false or misleading misrepresentations and warranties when made or when deemed made). Except as set forth on Schedule 5.10(a)(i) or in the Compliance Certificate delivered for the last month of the most recently ended fiscal quarter in accordance with Section 7.1(d), (A) to the knowledge of the Borrower, each item of owned Current Company IP is valid, subsisting and (other than with respect to expired or pending applications, including Patent applications) enforceable and no such item of Current Company IP has lapsed, expired, been cancelled or invalidated or become abandoned or unenforceable other than in the normal course of prosecuting Current Company IP or in connection with a Permitted Transfer, and (B) no written notice has been received challenging the inventorship or ownership, or relating to any lapse, expiration, invalidation, abandonment or unenforceability, of any such item of Current Company IP. Except as set forth on Schedule 5.10(a)(ii) or in the Compliance Certificate delivered for the last month of the most recently ended fiscal quarter in accordance with Section 7.1(d), (A) each such item of Current Company IP which

is exclusively licensed from another Person is valid, subsisting and (other than with respect to expired or pending applications, including Patent applications) enforceable and no such item of Current Company IP has lapsed, expired, been canceled or invalidated, or become abandoned or unenforceable other than in the normal course of prosecuting Current Company IP, and (B) no written notice has been received challenging the inventorship or ownership, or relating to any lapse, expiration, invalidation, abandonment or unenforceability, of any such item of Current Company IP. To the knowledge of any Loan Party, there are no published valid Patents, Patent applications, articles or prior art references that would reasonably be expected to materially adversely affect the exploitation of the Borrower Products. Except as set forth on Schedule 5.10(a)(x)-(y) or in the Compliance Certificate delivered for the last month of the most recently ended fiscal quarter in accordance with Section 7.1(d) (provided that such disclosure made in such Compliance Certificate shall not apply to a period covered by a prior Compliance Certificate and shall not cure any default arising from any false or misleading misrepresentations and warranties when made or when deemed made), (x) each Person who has or has had any rights in or to owned Current Company IP or any trade secrets owned by Borrower or any of its Subsidiaries, including each inventor named on the Patents within such owned Current Company IP filed by Borrower or any of its Subsidiaries has executed an agreement assigning directly or indirectly his, her or its entire right, title and interest in and to such owned Current Company IP and such trade secrets, and the inventions, improvements, discoveries, writings, works of authorship, information and other intellectual property embodied, described or claimed therein, to the stated owner thereof (or is expected to execute such agreement in due course), and (y) no such Person has any contractual or other obligation that would preclude or conflict with such assignment or the exploitation of the Borrower Products or entitle such Person to ongoing payments.

(b) (i) Borrower or any of its Subsidiaries possesses valid title to the Current Company IP for which it is listed as the owner or co-owner, as applicable, on Schedule 5.10(a); and (ii) there are no Liens on any Current Company IP (other than Permitted Liens).

(c) There are no material maintenance, annuity or renewal fees that are currently overdue beyond their allotted grace period for any of the Current Company IP which is owned or exclusively licensed to Borrower or any of its Subsidiaries, nor have any applications or registrations therefore, on account of such overdue fees, lapsed or become abandoned, been cancelled or expired in a manner that is not readily correctable. There are no material maintenance, annuity or renewal fees that are currently overdue beyond their allotted grace period for any of the Current Company IP which is non-exclusively licensed to Borrower or any of its Subsidiaries, nor have any material applications or registrations therefor lapsed or become abandoned, been canceled or expired.

(d) There are no unpaid fees or royalties under any Material Agreements concerning Current Company IP exclusively licensed to Borrower or any of its Subsidiaries ("Material IP Agreements"), that have become due, or are expected to become overdue and, each such Material IP Agreement is in full force and effect and is legal, valid, binding and enforceable in accordance with its respective terms, except as may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws relating to or limiting creditors' rights generally or by equitable principles relating to enforceability. Except as set forth on Schedule 5.10(d) or in the Compliance Certificate delivered for the last month of the most recently ended fiscal quarter in accordance with Section 7.1(d), neither Borrower nor any of its Subsidiaries, as applicable, is in breach of or default in any manner that could reasonably be expected to materially affect the Borrower Products under any Material Agreement to which it is a party or may otherwise be bound, and to the knowledge of each Loan Party no circumstances or grounds exist that would give rise to a claim of breach or right of rescission, termination, non-renewal, revision or amendment of any of the Material Agreements,

including the execution, delivery and performance of this Agreement and the other Loan Documents.

(e) To Borrower's knowledge, no payments by Borrower or any of its Subsidiaries are due to any other Person in respect of the Current Company IP, other than pursuant to the Material IP Agreements and those fees payable to patent offices in connection with the prosecution and maintenance of the Current Company IP, any applicable taxes and associated attorney fees.

(f) Neither Borrower nor any of its Subsidiaries has undertaken or omitted to undertake any acts, and to the knowledge of each Loan Party no circumstance or grounds exist that would invalidate or reduce, in whole or in part, the enforceability of (i) the Current Company IP in any manner that could reasonably be expected to materially adversely affect the Borrower Products, or (ii) in the case of Current Company IP owned or co-owned or exclusively licensed by Borrower or any of its Subsidiaries, except as set forth on Schedule 5.10(f) or in the Compliance Certificate delivered for the last month of the most recently ended fiscal quarter in accordance with Section 7.1(d), Borrower's or Subsidiary's entitlement to own or license and exploit such Current Company IP.

(g) Except as described on Schedule 5.9 or in the Compliance Certificate delivered for the last month of the most recently ended fiscal quarter in accordance with Section 7.1(d), with respect to Current Company IP there is no requested, filed pending, decided or settled opposition, interference proceeding, reissue proceeding (other than reissue proceedings in the normal course of prosecuting Current Company IP), reexamination proceeding, inter-partes review proceeding, post-grant review proceeding, cancellation proceeding, injunction, litigation, paragraph IV patent certification or lawsuit under the Hatch-Waxman Act, hearing, investigation, complaint, arbitration, mediation, demand, International Trade Commission investigation, decree or any other dispute, disagreement, or claim, in each case alleged in writing to Borrower or any of its Subsidiaries (collectively referred to hereinafter as "Specified Disputes"), nor to the knowledge of any Loan Party, has any such Specified Dispute been threatened in writing, in each case challenging the legality, validity, enforceability or ownership of any Current Company IP, in each case that would have a Material Adverse Effect on the Borrower Products.

(h) In each case where an issued Patent within the Current Company IP is owned or co-owned by Borrower or any of its Subsidiaries by assignment, the assignment has been or will be in due course duly recorded with the U.S. Patent and Trademark Office.

(i) Except as set forth on Schedule 5.10(i) or in the Compliance Certificate delivered for the last month of the most recently ended fiscal quarter in accordance with Section 7.1(d) (provided that such disclosure made in such Compliance Certificate shall not apply to a period covered by a prior Compliance Certificate and shall not cure any default arising from any false or misleading misrepresentations and warranties when made or when deemed made), there are no pending or threatened (in writing) claims against Borrower or any of its Subsidiaries alleging (i) that any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of the Borrower Products in the United States of America infringes or violates (or in the past infringed or violated) the rights of any third parties in or to any valid intellectual property ("Third Party IP") or constitutes a misappropriation of (or in the past constituted a misappropriation of) any Third Party IP, or (ii) that any Current Company IP is invalid or unenforceable.

(j) Except as set forth on Schedule 5.10(j) or in the Compliance Certificate delivered for the last month of the most recently ended fiscal quarter in accordance with Section 7.1(d), the

manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of the Borrower Products does not, to the knowledge of any Loan Party, infringe or violate any issued or registered Third Party IP (including any issued Patent within the Third Party IP) or constitute a misappropriation of any Third Party IP, in each case, in a manner that could reasonably be expected to materially adversely affect the exploitation of the Borrower Products.

(k) Except as set forth on Schedule 5.10(k) or in the Compliance Certificate delivered for the last month of the most recently ended fiscal quarter in accordance with Section 7.1(d), there are no settlements, covenants not to sue, consents, judgments, or orders which: (i) materially restrict the rights of Borrower or any of its Subsidiaries to use any Intellectual Property relating to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of the Borrower Products (in order to accommodate any Third Party IP or otherwise), or (ii) permit any third parties to use any Company IP in manner that would impair or hinder development of the Borrower Products.

(l) [Reserved].

(m) Borrower and each of its Subsidiaries have taken commercially reasonable measures customary in the biopharmaceutical industry to protect the confidentiality of all trade secrets owned by Borrower or any of its Subsidiaries or used or held for use by Borrower or any of its Subsidiaries, in each case relating to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of the Borrower Products.

(n) [Reserved].

(o) Except as described on Schedule 5.10(o) or in the Compliance Certificate delivered for the last month of the most recently ended fiscal quarter in accordance with Section 7.1(d), each Loan Party has all rights with respect to Intellectual Property necessary, other than any rights that would not be expected to cause a Material Adverse Effect, with respect to Current Company IP material in the operation or conduct of such Loan Party's business as currently conducted and proposed to be conducted by such Loan Party. Without limiting the generality of the foregoing, and in the case of Licenses, except for restrictions that are unenforceable under Article 9 of the UCC or are customary restrictions in exclusive Permitted Out-Licenses, each Loan Party has the right, to the extent required to operate such Loan Party's business, to freely transfer, license or assign Intellectual Property owned by such Loan Party and material in the operation or conduct of such Loan Party's business as currently conducted and proposed to be conducted by such Loan Party, without condition, restriction or payment of any kind (other than license payments in the ordinary course of business) to any third party. To Borrower's knowledge, each Loan Party owns or has the right to use, pursuant to valid licenses, all software development tools, library functions, compilers and all other third-party software and other items that are material to such Loan Party's business and used in the design, development, promotion, sale, license, manufacture, import, export, use or distribution of Borrower Products that are material to such Loan Party's business, in each case, except customary covenants in inbound license agreements and equipment leases where such Loan Party is the licensee or lessee.

(p) To Borrower's knowledge, no material software or other materials used by any Loan Party or any of their Subsidiaries (or used in any Borrower Products) are subject to an open-source or similar license (including but not limited to the General Public License, Lesser General Public License, Mozilla Public License, or Affero License) in a manner that would cause such

software or other materials to have to be (i) distributed to third parties at no charge or a minimal charge (royalty-free basis); (ii) licensed to third parties to modify, make derivative works based on, decompile, disassemble, or reverse engineer; or (iii) used in a manner that requires disclosure or distribution in source code form.

5.11 Borrower Products. Except as set forth on Schedule 5.11 or in the Compliance Certificate delivered for the last month of the most recently ended fiscal quarter in accordance with Section 7.1(d), no Intellectual Property owned by Borrower and material in its business or Borrower Product has been or is subject to any actual or, to the knowledge of Borrower, threatened in writing, litigation, third party proceeding (including any third party proceeding in the United States Patent and Trademark Office or any corresponding foreign office or agency) or outstanding decree, order, judgment, settlement agreement or stipulation that restricts in any manner Borrower's use, transfer or licensing thereof or that could reasonably be expected to adversely affect the validity, use or enforceability thereof. There is no decree, order, judgment, agreement, stipulation, arbitral award or other provision entered into in connection with any litigation or third party proceeding that obligates Borrower to grant licenses or ownership interest in any future Intellectual Property related to the operation or conduct of the business of Borrower or Borrower Products to an extent that could reasonably be expected to materially adversely affect such Loan Party's ability to perform or pay the Secured Obligations in accordance with the Loan Documents. Borrower has not received any written notice or claim, or, to the knowledge of Borrower, oral notice or claim, challenging or questioning Borrower's ownership in any material Intellectual Property (or written notice of any claim challenging or questioning the ownership in any licensed Intellectual Property of the owner thereof) or suggesting that any third party has any claim of legal or beneficial ownership with respect thereto nor, to Borrower's knowledge, is there a reasonable basis for any such claim.

5.12 Financial Accounts. Exhibit D, as may be updated by Borrower in a written notice provided to Agent after the Closing Date, is a true, correct and complete list of (a) all banks and other financial institutions at which Borrower or any Subsidiary maintains Deposit Accounts and (b) all institutions at which Borrower or any Subsidiary maintains an account holding Investment Property, and such exhibit correctly identifies the name, address and telephone number of each bank or other institution, the name in which the account is held, a description of the purpose of the account, and the complete account number therefor. None of the Loan Parties or any of their Subsidiaries owns or holds any Digital Assets.

5.13 Employee Loans. Except for loans constituting Permitted Investments or as described on Schedule 5.13, Borrower has no outstanding loans to any employee, officer or director of Borrower nor has Borrower guaranteed the payment of any loan made to an employee, officer or director of Borrower by a third party.

5.14 Capitalization and Subsidiaries. Borrower does not own any stock, partnership interest or other securities of any Person, except for Permitted Investments. Attached as Schedule 5.14, as may be updated by Borrower in a written notice provided after the Closing Date, is a true, correct and complete list of each Subsidiary.

5.15 Solvency. The fair salable value of Borrower's consolidated assets (including goodwill minus disposition costs) exceeds the fair value of Borrower's liabilities; Borrower is not left with unreasonably small capital after the transactions in this Agreement; and Borrower, and Borrower and each of its Subsidiaries (on a consolidated basis), are able to pay their debts (including trade debts) as they mature. The amount of any contingent liability at any time shall be computed as the amount that would reasonably be expected to become an actual and matured liability.

SECTION 6. INSURANCE; INDEMNIFICATION

6.1 Coverage. Borrower shall cause to be carried and maintained commercial general liability insurance covering Borrower and its Subsidiaries, on an occurrence form, against risks and in such amounts customarily insured against in Borrower's line of business. Such risks shall include the risks of bodily injury, including death, property damage, personal injury, and contractual liability per the terms of the indemnification agreement found in Section 6.3. Borrower must maintain a minimum of [**] Dollars ($[**]) of commercial general liability insurance for each occurrence. Borrower maintains and shall continue to maintain a minimum of [**] Dollars ($[**]) of directors' and officers' insurance for each occurrence and [**] Dollars ($[**]) in the aggregate. Until the Secured Obligations are Paid in Full, Borrower shall also cause to be carried and maintained insurance upon the business and assets of Borrower and its Subsidiaries, insuring against all risks of physical loss or damage howsoever caused, in an amount not less than the full replacement cost of the Collateral, provided that such insurance may be subject to standard exceptions and deductibles. If Borrower fails to obtain the insurance called for by this Section 6.1 or fails to pay any premium thereon or fails to pay any other amount which Borrower is obligated to pay under this Agreement or any other Loan Document or which may be required to preserve the Collateral, Agent may obtain such insurance or make such payment, and all amounts so paid by Agent are immediately due and payable, bearing interest at the then highest rate applicable to the Secured Obligations, and secured by the Collateral. Agent will make reasonable efforts to provide Borrower with notice of Agent obtaining such insurance at the time it is obtained or within a reasonable time thereafter. No payments by Agent are deemed an agreement to make similar payments in the future or Agent's waiver of any Event of Default.

6.2 Certificates. Borrower shall deliver to Agent certificates of insurance that evidence Borrower's compliance with its insurance obligations in Section 6.1 and the obligations contained in this Section 6.2: (i) on the Closing Date, and (ii) thereafter, on the date of delivery of each Compliance Certificate delivered for the last month of a fiscal quarter policy renewal or modification after the Closing Date that results in newly issued certificates. Borrower's insurance certificate shall reflect Agent (shown as "Hercules Capital, Inc., as Agent, and its successors and/or assigns") is an additional insured for commercial general liability, a lenders loss payable for all risk property damage insurance, subject to the insurer's approval, and a lenders loss payable for property insurance and additional insured for liability insurance for any future insurance that Borrower may acquire from such insurer. Attached to the certificates of insurance will be additional insured endorsements for liability and lender's loss payable endorsements for all risk property damage insurance. All certificates of insurance will provide for a minimum of thirty (30) days advance written notice to Agent of cancellation (other than cancellation for non-payment of premiums, for which ten (10) days' advance written notice shall be sufficient) or any other change adverse to Agent's interests. Any failure of Agent to scrutinize such insurance certificates for compliance is not a waiver of any of Agent's rights, all of which are reserved. At Agent's request, Borrower shall provide Agent with copies of each insurance policy, and upon entering into or amending any insurance policy required hereunder in any material respect, Borrower shall, on or before the date of the delivery of each Compliance Certificate delivered for the last month of a fiscal quarter following such entry or amendment, provide Agent with updated insurance certificates with respect to such policies, and, upon Agent's request, copies of such policies.

6.3 Indemnity. Borrower agrees to indemnify and hold Agent, Lenders and their officers, directors, employees, agents, in-house attorneys, representatives and shareholders (each, an "Indemnified Person") harmless from and against any and all third-party claims, costs, expenses, damages and liabilities (including such claims, costs, expenses, damages and liabilities based on liability in tort, including strict liability in tort), including reasonable and documented out-of-pocket

attorneys' fees and out-of-pocket disbursements and other costs of investigation or defense (including those incurred upon any appeal) (collectively, "Liabilities"), that may be instituted or asserted against or incurred by such Indemnified Person as the result of credit having been extended, suspended or terminated under this Agreement and the other Loan Documents or the administration of such credit, or in connection with or arising out of the transactions contemplated hereunder and thereunder, or any actions or failures to act in connection therewith, or arising out of the disposition or utilization of the Collateral, excluding in all cases Liabilities to the extent such Liabilities arise solely out of gross negligence or willful misconduct of any Indemnified Person or changes in income tax rates. This Section 6.3 shall not apply with respect to Taxes other than any Taxes that represent losses, claims, damages, etc. arising from any non-Tax claim. In no event shall any Indemnified Person be liable on any theory of liability for any special, indirect, consequential or punitive damages (including any loss of profits, business or anticipated savings). This Section 6.3 shall survive the repayment of indebtedness under, and otherwise shall survive the expiration or other termination of, this Agreement, in each case, subject to the applicable statute of limitations.

SECTION 7. COVENANTS OF BORROWER

Borrower agrees as follows:

7.1 Financial Reports. Borrower shall furnish to Agent the financial statements and reports listed hereinafter (the "Financial Statements"):

(a) as soon as practicable (and in any event within thirty (30) days) after the end of each month, unaudited interim and year-to-date financial statements as of the end of such month (prepared on a consolidated), including balance sheet and related statements of income and cash flows, all certified by a duly authorized officer of Borrower to the effect that they have been prepared in accordance with GAAP, except (i) for the absence of footnotes, (ii) that they are subject to normal year-end adjustments, and (iii) they do not contain certain non-cash items that are customarily included in quarterly and annual financial statements;

(b) as soon as practicable (and in any event within forty-five (45) days) after the end of each calendar quarter), unaudited interim and year-to-date financial statements as of the end of such calendar quarter (prepared on a consolidated basis), including balance sheet and related statements of income and cash flows, certified by a duly authorized officer of Borrower to the effect that they have been prepared in accordance with GAAP, except (i) for the absence of footnotes, and (ii) that they are subject to normal year-end adjustments;

(c) as soon as practicable (and in any event within ninety (90) days) after the end of each fiscal year, audited financial statements as of the end of such year (prepared on a consolidated basis), including balance sheet and related statements of income and cash flows, and setting forth in comparative form the corresponding figures for the preceding fiscal year, certified without qualification (other than any going concern qualification) by Deloitte & Touche LLP or another firm of independent certified public accountants selected by Borrower and reasonably acceptable to Agent, accompanied by any management report from such accountants;

(d) as soon as practicable (and in any event within thirty (30) days) after the end of each month, a Compliance Certificate;

(e) as soon as practicable (and in any event within thirty (30) days) after the end of each month, a report showing agings of accounts receivable and accounts payable;

(f) promptly after the sending or filing thereof, as the case may be, copies of any proxy statements, financial statements, information or reports that Company has made available to holders of its common stock and copies of any regular, periodic and special reports or registration statements that Company files with the Securities and Exchange Commission or any Governmental Authority that may be substituted therefor, or any national securities exchange;

(g) upon Agent's request, copies of any material Governmental Approvals obtained by Borrower or any of its Subsidiaries;

(h) promptly upon the request of Agent or Lender at any time after the achievement of Approval Milestone 1 or Approval Milestone 2, the most recently available materials that the Borrower provides to its directors detailing key metrics relating to Borrower's commercial performance;

(i) financial and business projections promptly following their approval by Company's Board of Directors at the end of each fiscal year, and in any event, within sixty (60) days after the end of Borrower's fiscal year, as well as budgets, operating plans and other financial information reasonably requested by Agent;

(j) on the date of delivery of any Compliance Certificate delivered for the last month of a fiscal quarter, insurance renewal statements of insurance policies required to be maintained in accordance with Section 6.1;

(k) prompt notice of any legal process that is reasonably likely to result in damages, expenses or liabilities of Borrower in excess of [**] Dollars ($[**]); and

(l) prompt (but in any event no more than two (2) Business Days') notice if Borrower or any Subsidiary has knowledge that Borrower, or any Subsidiary or Affiliate of Borrower, is listed on the OFAC Lists or (a) is convicted on, (b) pleads *nolo contendere* to, (c) is indicted on, or (d) is arraigned and held over on charges involving money laundering or predicate crimes to money laundering.

Borrower shall not (without the consent of Agent, such consent not to be unreasonably withheld or delayed), make any change in its (a) accounting policies or reporting practices, except as required by GAAP or pursuant to applicable securities laws or regulations of the SEC or (b) fiscal years or fiscal quarters. The fiscal year of Borrower shall end on December 31.

The executed Compliance Certificate, and all Financial Statements required to be delivered hereunder shall be sent per instructions (i) specified on Addendum 2 or (ii) otherwise provided by Agent to Borrower via a written notice from time to time.

Notwithstanding the foregoing, documents required to be delivered under Sections 7.1(a), (b), (c), (f) or (k) (to the extent any such documents are included in materials otherwise filed with the SEC) may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date on which Borrower makes such documented publicly available.

7.2 Management Rights. Borrower shall permit any representative that Agent or Lenders authorizes, including its attorneys and accountants, to inspect the Collateral and examine and make copies and abstracts of the books of account and records of Borrower at reasonable times and upon reasonable notice during normal business hours; provided, however, that so long as no Event of Default has occurred and is continuing, such examinations shall be limited to no more often

than once per fiscal year. In addition, in connection with such inspections, any such representative shall have the right to meet with management and officers of Borrower to discuss such books of account and records at such time. In addition, Agent or Lenders shall be entitled at reasonable times and intervals to consult with and advise the management and officers of Borrower concerning significant business issues affecting Borrower. Such consultations shall not unreasonably interfere with Borrower's business operations. The parties intend that the rights granted Agent and Lenders shall constitute "management rights" within the meaning of 29 C.F.R. Section 2510.3-101(d)(3)(ii), but that any advice, recommendations or participation by Agent or Lenders with respect to any business issues shall not be deemed to give Agent or Lenders, nor be deemed an exercise by Agent or Lenders of, control over Borrower's management or policies.

7.3 Further Assurances. Borrower shall, and shall cause each other Loan Party to, from time to time execute, deliver and file, alone or with Agent, any financing statements, security agreements, collateral assignments, notices, control agreements, promissory notes or other documents to perfect, give the highest priority to Agent's Lien on the Collateral or otherwise evidence Agent's rights herein. Borrower shall from time to time procure any instruments or documents as may be reasonably requested by Agent, and take all further action that may be necessary, or that Agent may reasonably request, to perfect and protect the Liens granted hereby or pursuant to applicable Loan Documents. In addition, and for such purposes only, Borrower hereby authorizes Agent to execute and deliver on behalf of Borrower and to file such financing statements (including an indication that the financing statement covers "all assets or all personal property" of Borrower in accordance with Section 9-504 of the UCC), and Borrower hereby authorizes Agent, at any time during the existence of an Event of Default, to execute and deliver on behalf of Borrower any collateral assignments, notices, control agreements, security agreements and other documents without the signature of Borrower either in Agent's name or in the name of Agent as agent and attorney-in-fact for Borrower. Borrower shall, in good faith and in its reasonable commercial discretion, in each case, subject to the terms of this Agreement, protect and defend Borrower's title to the Collateral and Agent's Lien thereon against all Persons claiming any interest adverse to Borrower or Agent other than Permitted Liens.

7.4 Indebtedness. Borrower shall not create, incur, assume, guarantee or be or remain liable with respect to any Indebtedness, or permit any Subsidiary to do so, other than Permitted Indebtedness, or prepay any Indebtedness or take any actions which impose on Borrower an obligation to prepay any Indebtedness, except for (a) the conversion of Indebtedness into equity securities and the payment of cash in lieu of fractional shares in connection with such conversion, (b) purchase money Indebtedness or Indebtedness in respect of capital leases permitted hereunder pursuant to its then applicable payment schedule, (c) prepayment by any Subsidiary of (i) inter-company Indebtedness owed by such Subsidiary to any Borrower, or (ii) if such Subsidiary is not a Borrower, intercompany Indebtedness owed by such Subsidiary to another Subsidiary that is not a Borrower, (d) payments made on Subordinated Indebtedness to the extent permitted under the relevant Subordination Agreement, (e) the issuance of and performance of obligations under Permitted Convertible Debt, (f) the conversion, exchange, exercise, repurchase, redemption of Permitted Convertible Debt, or the exercise or early unwind or termination of Permitted Bond Hedge Transactions and Permitted Warrant Transactions, in each case so long as any cash prepayments made by Borrower in connection therewith are Permitted Convertible Debt Financing Payments, (g) Indebtedness owed under corporate credit cards constituting Permitted Indebtedness and prepaid in the ordinary course of business, (h) Permitted Indebtedness with the proceeds of Permitted Indebtedness, (i) prepayment of Indebtedness permitted under clauses (i), (iv), (vii), and (~~xviii~~xix) of the definition of Permitted Indebtedness, or (j) as otherwise permitted hereunder or approved in writing by Agent. Notwithstanding the foregoing, payments constituting Thermo Fisher Installment Payments made in compliance with Section 7.25 shall be permitted.

7.5 Collateral. Borrower shall at all times (a) keep the Collateral and all other property and assets used in Borrower's business or in which Borrower now or hereafter holds any interest free and clear from any Liens whatsoever (except for Permitted Liens), and (b) shall give Agent prompt written notice of any Liens thereon (other than Permitted Liens). Borrower shall not agree with any Person other than Agent or Lenders not to encumber its property other than in connection with Permitted Liens. Borrower shall not enter into or suffer to exist or become effective any agreement that prohibits or limits the ability of any Borrower to create, incur, assume or suffer to exist any Lien upon any of its property (including Intellectual Property), whether now owned or hereafter acquired, to secure its obligations under the Loan Documents to which it is a party other than (i) this Agreement and the other Loan Documents, (ii) any agreements governing any purchase money Liens or capital lease obligations otherwise permitted hereby (in which case, any prohibition or limitation shall only be effective against the assets financed thereby), (iii) agreements governing cash collateral arrangements constituting Permitted Liens restricting Liens on cash collateral accounts and the Cash therein, ~~and~~ (iv) restrictions on the assignment of the Extended Payment Schedule, under and as defined in the Thermo Fisher Agreement and (v) customary restrictions on the assignment of leases, licenses and other agreements. Borrower shall cause its Subsidiaries to protect and defend such Subsidiary's title to its assets from and against all Persons claiming any interest adverse to such Subsidiary (other than Permitted Liens), and Borrower shall cause its Subsidiaries at all times to keep such Subsidiary's property and assets free and clear from any legal process or Liens whatsoever (except for Permitted Liens).

7.6 Investments. Borrower shall not directly or indirectly acquire or own, or make any Investment in or to any Person, or permit any of its Subsidiaries to do so, other than Permitted Investments. No Loan Party shall directly or indirectly acquire or own, nor make any Investment in Digital Assets, nor permit any of its Subsidiaries so to do. Notwithstanding the foregoing, and for the avoidance of doubt, this Section 7.6 shall not prohibit Permitted Convertible Debt Financing Payments.

7.7 Distributions. Borrower shall not, and shall not allow any Subsidiary to, (a) repurchase or redeem any class of stock or other Equity Interest other than pursuant to employee, director or consultant repurchase plans or other similar agreements, provided, however, in each case the repurchase or redemption price does not exceed the fair market value for such stock or Equity Interest unless required by the terms of such agreement or plan, or pursuant to a public repurchase of securities in compliance with the requirements of SEC Rule 10b-18, or (b) declare or pay any cash dividend or make any other cash distribution on any class of stock or other Equity Interest, except that a Subsidiary may pay dividends or make other distributions to Borrower or any Subsidiary of Borrower, or (c) except for Permitted Investments, lend money to any employees, officers or directors or guarantee the payment of any such loans granted by a third party in excess of [**] Dollars ($[**]) in the aggregate, or (d) convert any of its convertible securities into other securities pursuant to the terms of such convertible securities or otherwise in exchange thereof other than pursuant to the terms thereof so long as such conversion does not result in a Change of Control, or (e) waive, release or forgive any Indebtedness owed by any employees, officers or directors in excess of [**] Dollars ($[**]) in the aggregate other than cancellation of Indebtedness in connection with the repurchase of Equity Interests permitted under clause (a) above or clause (iii) of the definition of Permitted Investments. Notwithstanding the foregoing, payments constituting Thermo Fisher Installment Payments made in compliance with Section 7.25 shall be permitted.

Notwithstanding the foregoing, and for the avoidance of doubt, this Section 7.7 shall not prohibit Permitted Convertible Debt Financing in accordance with the terms of the Payments.

7.8 Transfers. Except for Permitted Transfers, Borrower shall not, and shall not permit any Subsidiary to, voluntarily or involuntarily transfer, sell, lease, license, lend or in any other manner convey ("Transfer") any equitable, beneficial or legal interest in any material portion of its assets (including, without limitation, pursuant to a Division); provided that licenses of Company IP (to the extent not constituting Permitted Transfers) may be made with the consent of the Required Lenders (such consent not to be unreasonably withheld or delayed). Notwithstanding the foregoing, and for the avoidance of doubt, this Section 7.8 shall not prohibit the conversion by holders of any Permitted Convertible Debt Financing in accordance with the terms of the indenture governing such Permitted Convertible Debt Financing or Borrower's delivery of the conversion consideration in connection therewith; provided that the conversion consideration (or exchange or inducement consideration) paid to such holders constitutes a Permitted Convertible Debt Financing Payment.

7.9 Mergers and Consolidations. Except for Permitted Acquisitions, Borrower shall not, nor will it permit any Subsidiary to, merge, dissolve, liquidate, consolidate with or into another Person, or dispose of (whether in one transaction or in a series of transactions) all or substantially all of its assets (whether now owned or hereafter acquired) to or in favor of any Person (other than mergers or consolidations of (a) a Subsidiary which is not a Borrower into another Subsidiary or into Borrower or (b) a Borrower into another Borrower).

7.10 Taxes. Borrower shall, and shall cause each of its Subsidiaries to, pay when due all material Taxes of any nature whatsoever now or hereafter imposed or assessed against Borrower or such Subsidiary or the Collateral or upon Borrower's (or such Subsidiary's) ownership, possession, use, operation or disposition thereof or upon Borrower's (or such Subsidiary's) rents, receipts or earnings arising therefrom. Borrower shall, and shall cause each of its Subsidiaries to, accurately file on or before the due date therefor (taking into account proper extensions) all federal and state income Tax returns and other material Tax returns required to be filed. Notwithstanding the foregoing, Borrower and its Subsidiaries may contest, in good faith and by appropriate proceedings diligently conducted, Taxes for which Borrower and its Subsidiaries maintain adequate reserves in accordance with GAAP.

7.11 Corporate Changes.

(a) Neither Borrower nor any Subsidiary shall change its corporate name, legal form or jurisdiction of formation without twenty (20) days' prior written notice to Agent.

(b) Neither Borrower nor any Subsidiary shall suffer a Change in Control.

(c) Neither Borrower nor any Subsidiary shall relocate its chief executive office or its principal place of business unless: (i) it has provided prior written notice to Agent; and (ii) such relocation shall be within the continental United States of America.

(d) If Borrower intends to add any new offices or business locations, including warehouses, containing any portion of Borrower's assets or property valued, individually or in the aggregate, in excess of [**] Dollars ($[**]) (other than offices, business locations or warehouses holding primarily (i) works-in-progress, raw materials or otherwise in the supply chain for commercial manufacturing or sale of Borrower Products, (ii) inventory or other goods in transit, or (iii) assets (other than equipment) in connection with clinical and pre-clinical studies, including contract manufacturing organizations, distribution service firms, contract research organizations, clinical sites, clinical investigators and other institutions), then Borrower will use commercially reasonable efforts to cause the landlord of any such new offices or business locations, including

warehouses, to execute and deliver a landlord consent in form and substance satisfactory to Agent within thirty (30) days.

(e) If Borrower intends to deliver any portion of Borrower's assets or property valued, individually or in the aggregate, in excess of [**] Dollars ($[**]) to a bailee (other than bailees or other third parties in possession of (i) works-in-progress, raw materials or otherwise in the supply chain for commercial manufacturing or sale of Borrower Products, (ii) inventory or other goods in transit, or (iii) assets (other than equipment) in connection with clinical and pre-clinical studies, including contract manufacturing organizations, distribution service firms, contract research organizations, clinical sites, clinical investigators and other institutions), and Agent and such bailee are not already parties to a bailee agreement governing both the Collateral and the location to which Borrower intends to deliver the Collateral, then Borrower will use commercially reasonable efforts to cause such bailee to execute and deliver a bailee agreement in form and substance satisfactory to Agent within thirty (30) days.

(f) The Borrower will not, and will not permit any Subsidiary to, engage to any material extent in any business other than those businesses conducted by the Borrower and its Subsidiaries on the date hereof or any business reasonably related or incidental thereto or representing a reasonable expansion thereof.

(g) Without the prior written consent of Agent, the Borrower will not make, or agree to make, any modification, amendment or waiver of any of the terms or provisions of Borrower's Organizational Documents that is adverse to Agent or any of the Lenders.

7.12 Deposit Accounts. No Loan Party shall maintain any Deposit Accounts, any accounts or sub-accounts in connection with an insured cash sweep program, or accounts holding Investment Property, except with respect to which Agent has an Account Control Agreement on terms and conditions satisfactory to Agent in its sole discretion, provided that no Account Control Agreement shall be required for (i) any Excluded Account or (ii) any other deposit accounts, so long as the aggregate amount in all such deposit accounts do not exceed [**] Dollars ($[**]) on any day. None of the Loan Parties or any of their Subsidiaries shall own or hold any Digital Assets.

7.13 Joinder of Subsidiaries. Borrower shall notify Agent of each Subsidiary formed or acquired subsequent to the Closing Date (including any new Subsidiary formed by Division) and, within thirty (30) days of such formation or acquisition (or such longer period of time as agreed to by Agent in writing in its sole discretion), shall cause any such Subsidiary (other than an Excluded Subsidiary) to execute and deliver to Agent a Joinder Agreement and such other documents and instruments as shall be requested by Agent to effectuate the transactions contemplated by such Joinder Agreement (in each case in form and substance acceptable to Agent), or, if requested by Agent, a Guaranty and appropriate collateral security documents to secure the obligations pursuant to such Guaranty (in each case in form and substance acceptable to Agent); it being agreed that if such new Subsidiary is formed by a Division, the foregoing requirements shall be satisfied substantially concurrently with the formation of such Subsidiary. In the event one or more Subsidiaries that were previously Excluded Subsidiaries no longer qualify as an Excluded Subsidiary, such Subsidiaries shall be subject to the requirements of the immediately preceding sentence.

7.14 Regulatory and Product Notices. The Borrower, on behalf of the Loan Parties, shall promptly (but in any event within ten (10) Business Days) after the receipt or occurrence thereof notify Agent of:

(a) any written notice that the FDA (or international equivalent) is limiting, suspending or revoking any Registration (including, but not limited to, by the issuance of a clinical hold),

(b) any written notice from a Governmental Authority that a Loan Party or its Subsidiaries has become subject to any regulatory action,

(c) any written notice from the FDA indicating the exclusion or debarment from any governmental healthcare program or debarment or disqualification by FDA (or international equivalent) of any Loan Party or its Subsidiaries,

(d) any written notice from a Governmental Authority that a Loan Party or any Subsidiary, or any of their licensees or sublicensees (including licensees or sublicensees under any Material Agreement), is being investigated or is the subject of any allegation of potential or actual violations of any FDA Laws,

(e) any written notice from a Governmental Authority that any Borrower Product has been seized, withdrawn, recalled, detained, or subject to a suspension of manufacturing, or the commencement of any proceedings in the United States or any other jurisdiction seeking the withdrawal, recall, suspension, import detention, or seizure of any Borrower Product are pending or threatened in writing against Borrower or its Subsidiaries, or

(f) any written notice from the FDA narrowing or otherwise limiting the scope of marketing authorization or the labeling of the products of any Loan Party and its Subsidiaries under any Registration;

except, in each case of (a) through (f) above, where such action would not reasonably be expected to have, either individually or in the aggregate, any Material Regulatory Liabilities.

7.15 Notification of Event of Default. Borrower shall notify Agent promptly (but in any event within two (2) Business Days after the occurrence) of the occurrence of any Event of Default.

7.16 SBA. One or more affiliates of Agent have received a license from the U.S. Small Business Administration ("SBA") to extend loans as a small business investment company ("SBIC") pursuant to the Small Business Investment Act of 1958, as amended, and the associated regulations, as amended (collectively, the "SBIC Act"). Portions of the Loan to Borrower may be made by a Lender that is a SBIC. Addendum 3 to this Agreement outlines various responsibilities of Agent, each Lender and Borrower associated with a loan made by a SBIC, and such Addendum 3 is hereby incorporated in this Agreement. Borrower shall immediately notify Agent of any failure to comply with its obligations under Addendum 3 upon acquiring knowledge thereof.

7.17 Use of Proceeds. Borrower agrees that the proceeds of the Loans shall be used solely to pay related fees and expenses in connection with this Agreement and for working capital and general corporate purposes. The proceeds of the Loans will not be used in violation of Anti-Corruption Laws or applicable Sanctions.

7.18 MSC Investment Conditions. At any time that the MSC Subsidiary has any assets or liabilities, Borrower shall satisfy the MSC Investment Conditions at all times.

7.19 Material Agreement. Borrower shall give prompt (and in any event within ten (10) Business Days) written notice to Agent of entering into a Material Agreement or materially

amending or terminating a Material Agreement; provided that to the extent disclosure of any such Material Agreement, material amendment or termination is included in materials otherwise filed with the SEC, such notice shall be deemed to have been delivered on the date on which Borrower makes such disclosure publicly available.

7.20 Compliance with Laws.

(a) Borrower (i) shall maintain, and shall cause its Subsidiaries to maintain, compliance in all material respects with all applicable laws, rules or regulations (including any law, rule or regulation with respect to the making or brokering of loans or financial accommodations), and (ii) shall, or cause its Subsidiaries to, obtain and maintain all required governmental authorizations, approvals, licenses, franchises, permits or registrations reasonably necessary in connection with the conduct of Borrower's business. Borrower shall not become an "investment company," a company that would be an "investment company" except for the exclusion from the definition of "investment company" in Section 3(c) of the 1940 Act, or a company controlled by an "investment company" under the 1940 Act, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation X, T and U of the Federal Reserve Board of Governors).

(b) Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries permit any controlled Affiliate to, directly or indirectly, knowingly enter into any documents, instruments, agreements or contracts with any Person listed on the OFAC Lists. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries, permit any controlled Affiliate to, directly or indirectly, (i) conduct any business or engage in any transaction or dealing with any Blocked Person, including, without limitation, the making or receiving of any contribution of funds, goods or services to or for the benefit of any Blocked Person, (ii) deal in, or otherwise engage in any transaction relating to, any property or interests in property blocked pursuant to Executive Order No. 13224 or any similar executive order or other Anti-Terrorism Law, or (iii) engage in or conspire to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in Executive Order No. 13224 or other Anti-Terrorism Law.

(c) Borrower has implemented and shall maintain in effect policies and procedures designed to ensure compliance by Borrower, its Subsidiaries and their respective directors, officers, employees and agents with Anti-Corruption Laws and applicable Sanctions, and Borrower, its Subsidiaries and their respective officers and employees and to the knowledge of Borrower its directors and agents, are in compliance with Anti-Corruption Laws and applicable Sanctions in all material respects.

(d) None of Borrower, any of its Subsidiaries or any of their respective directors, officers or employees, or to the knowledge of Borrower, any agent for Borrower or its Subsidiaries that will act in any capacity in connection with or benefit from the credit facility established hereby, is a Sanctioned Person. No Loan, use of proceeds or other transaction contemplated by this Agreement will violate Anti-Corruption Laws or applicable Sanctions.

7.21 Financial Covenant.

(a) Minimum Cash. Beginning on the Initial Minimum Cash Test Date and at all times thereafter, Borrower shall maintain Qualified Cash in an amount greater than or equal to the outstanding principal amount of the Secured Obligations, multiplied by (i) prior to Borrower's achievement of either the Approval Milestone I or the Approval Milestone II, sixty percent (60%),

and (ii) from and after Borrower's achievement of either the Approval Milestone I or the Approval Milestone II (the "Initial Cash Stepdown"), [**] percent ([**]%) (as applicable, the "Minimum Cash Coverage Percentage"); provided, that, upon Borrower's achievement of the Initial Cash Stepdown and the Commercial Milestone, the Minimum Cash Coverage Percentage shall be reduced to [**] percent ([**]%); provided further that, if Borrower has not achieved either Data Milestone ~~1~~I or Data Milestone ~~2~~II on or before [**], then beginning on [**] the Minimum Cash Coverage Percentage shall be increased to [**] percent ([**]%) until such time as Borrower achieves either Approval Milestone I or the Approval Milestone II, at which time it shall be decreased to [**] percent ([**]%) and further decreased to [**] percent ([**]%) upon Borrower's achievement of the Initial Cash Stepdown and the Commercial Milestone. Notwithstanding the foregoing, this Section 7.21(a) shall not be required to be complied with at any time in which Company's Market Capitalization for such day is greater than One Billion Six Hundred Fifty Million Dollars ($1,650,000,000).

If any Loan Party makes a cash payment in respect of Permitted Convertible Debt utilizing the Redemption Conditions, Borrower shall, at all times thereafter, maintain Qualified Cash in an amount equal to no less than [**] percent ([**]%) of the Secured Obligations (inclusive of any Prepayment Charge and End of Term Charge that would be due and owing if the outstanding Term Loan Advances were prepaid at the time of measurement).

(b) Minimum Revenue. Beginning on the Initial Minimum Revenue Test Date and tested monthly thereafter, Borrower shall generate Net Product Revenue, measured on a trailing six (6) month basis, of at least [**] percent ([**]%) of the Net Product Revenue included in the Board Approved Forecast for the trailing six (6) month period ending on the last day of such month. Notwithstanding the foregoing, this Section 7.21(b) shall not be required to be complied with for any particular month to the extent that for each day during such month, either (i) Borrower maintains Qualified Cash in an amount greater than or equal to the outstanding principal amount of the Secured Obligations, or (ii) (x) Company's Market Capitalization for such day is greater than One Billion Six Hundred Fifty Million Dollars ($1,650,000,000), and (y) Borrower maintains Qualified Cash in an amount greater than or equal to the outstanding principal amount of the Secured Obligations, multiplied by fifty percent (50%).

7.22 Intellectual Property. Each Borrower shall (i) use commercially reasonable efforts protect, defend and maintain the validity and enforceability of Current Company IP, except in connection with transactions permitted by clause (ix) of Permitted Transfers and (ii) not allow any Intellectual Property material to Borrowers' business to be abandoned (other than in the normal course of prosecution whereby, for example, an application is abandoned in favor of a continuation or divisional application), forfeited or dedicated to the public without Agent's written consent, except in connection with transactions permitted by clause (ix) of Permitted Transfers. If a Borrower (a) obtains any Patent, registered Trademark, registered Copyright, registered mask work, or any pending application for any of the foregoing, whether as owner, licensee or otherwise, or (b) applies for any Patent or the registration of any Trademark, then such Borrower shall concurrently with the delivery of each Compliance Certificate delivered for the last month of a fiscal quarter, provide written notice thereof to Agent and shall execute such intellectual property security agreements (unless such application for Patent is a continuing or divisional application of preexisting Current Company IP) and other documents and take such other actions as Agent may request in its good faith business judgment to perfect and maintain a first priority perfected security interest in favor of Agent in such property; *provided* that, for the avoidance of doubt, (a) and (b) shall not require Borrower to record intellectual security agreements with government offices, such as the USPTO, for Patents and Trademarks but rather Agent's responsibility to record after Borrower execution (if any). If a Borrower decides to register any Copyrights or mask works in the United States Copyright

Office, such Borrower shall: (x) provide Agent written notice concurrently with the delivery of each Compliance Certificate delivered for the last month of a fiscal quarter of such Borrower's intent to register such Copyrights or mask works together with a copy of the application it intends to file with the United States Copyright Office (excluding exhibits thereto) and (y) execute an intellectual property security agreement and such other documents and take such other actions as Agent may request in its good faith business judgment to perfect and maintain a first priority perfected security interest in favor of Agent in the Copyrights or mask works intended to be registered with the United States Copyright Office; and (z) record such intellectual property security agreement with the United States Copyright Office contemporaneously with filing the Copyright or mask work application(s) with the United States Copyright Office.

7.23 Transactions with Affiliates. Except as otherwise described on Schedule 7.23, Borrower shall not, and shall not permit any Subsidiary to, directly or indirectly, enter into or permit to exist any transaction of any kind with any Affiliate of Borrower or such Subsidiary, other than transactions (a) among Loan Parties, (b) on terms that are less favorable to Borrower or such Subsidiary, as the case may be, than those that might be obtained in an arm's length transaction from a Person who is not an Affiliate of Borrower or such Subsidiary, (c) to the extent approved by Borrower's board of directors or a duly authorized committee thereof or a duly authorized officer of Borrower, the payment of reasonable fees to directors of Borrower who are not employees of Borrower or any Subsidiary, and compensation and employee benefit arrangements paid to, and indemnities provided for the benefit of, and severance, separation and consulting agreements or arrangements entered into with, directors, officers or employees of Borrower or its Subsidiaries in the ordinary course of business, (d) the sale and issuance of Borrower's Qualified Equity Interests to Affiliates in a transaction not resulting in a Change in Control, and (e) intercompany transactions expressly permitted by Section 7.

7.24 Permitted Convertible Debt Financing Payments.

(a) Make or permit any payment on Permitted Convertible Debt Financing except (i) interest payments in accordance with the terms of the indenture governing such Permitted Convertible Debt Financing, (ii) Borrower's delivery of conversion consideration in connection with the conversion by holders of any Permitted Convertible Debt Financing in accordance with the terms of the indenture governing such Permitted Convertible Debt Financing or the delivery of Common Stock and Cash in lieu of fractional shares of Common Stock to induce the conversion of Permitted Convertible Debt Financing; provided that the conversion consideration (or inducement consideration) paid to such holders is limited to (A) Common Stock and (B) Cash in lieu of fractional shares of Common Stock, (iii) payments in connection with redemptions or repurchases permitted by Section 7.24(b), or (iv) any other payments if, before and after giving effect to such payments, the Redemption Conditions are satisfied.

(b) Redeem, repurchase or exchange any Permitted Convertible Debt Financing, except (i) the redemption or repurchase of Permitted Convertible Debt Financing in exchange for Common Stock and Cash in lieu of fractional shares of Common Stock; provided that the repurchase consideration paid to the holders of Permitted Convertible Debt Financing is limited to (A) Common Stock, (B) Cash in lieu of fractional shares of Common Stock, (ii) redemptions or repurchases with Cash if, before and after giving effect to such payments, the Redemption Conditions are satisfied, (iii) exchanges for a different series of Permitted Convertible Debt Financing, (iv) redemptions or repurchases with Cash in an amount that does not exceed the proceeds received by Borrower from the substantially concurrent issuance of Common Stock and/or Permitted Convertible Debt Financing (or a permitted refinancing thereof) plus the net cash proceeds, if any, received by Borrower pursuant to the related exercise or early unwind or

termination of the related Permitted Bond Hedge Transactions and Permitted Warrant Transactions, if any, pursuant to the immediately following proviso); provided that, substantially concurrently with, or a commercially reasonable period of time before or after, the related settlement date for the convertible notes issued in a Permitted Convertible Debt Financing that is so repurchased, exchanged or converted, Borrower shall exercise or unwind or terminate early (whether in cash, shares or any combination thereof) the portion of the Permitted Bond Hedge Transactions and Permitted Warrant Transactions, if any, corresponding to such Permitted Convertible Debt Financing that are so repurchased, exchanged or converted.

(c) In no event shall the foregoing permit Borrower to pay holders of Permitted Convertible Debt Financing any Cash (other than cash in lieu of fractional shares) in connection with mandatory repurchase rights granted to such holders upon the occurrence of a "change of control", "fundamental change", "make-whole fundamental change" or any comparable term, unless, before and after giving effect to such payments, the Redemption Conditions are satisfied.

(d) Notwithstanding anything to the contrary set forth in this Section 7.24, and for the avoidance of doubt: (i) Borrower may make any required payment of premium to a counterparty thereunder due in connection with entering into any Permitted Bond Hedge Transaction; (ii) Borrower may make any payment in connection with any Permitted Warrant Transaction by (1) delivery of shares of Borrower's Common Stock (together with cash in lieu of fractional shares) upon net share settlement thereof, (2) set-off, netting and/or payment of an early termination payment or other payment thereunder, in each case, in Borrower's Common Stock and (3) solely to the extent Borrower does not have the option of satisfying such payment obligations through the delivery of shares of Borrower's Common Stock or is otherwise required to satisfy such payment obligations in Cash, set-off, netting and/or payment of an early termination payment or other payment thereunder, in each case, in cash (it being understood and agreed that any payment made in Cash in connection with Permitted Warrant Transactions by set-off, netting and/or payment of an early termination payment or similar payment thereunder, in each case, after using commercially reasonable efforts to satisfy such obligation (or the portion thereof remaining after giving effect to any netting or set-off against termination or similar payments under an applicable Permitted Bond Hedge Transaction) by delivery of shares of Borrower's Common Stock shall be deemed to be a payment obligation required to be satisfied in Cash); and (iii) Borrower may acquire shares or other Equity Interests or cash or a combination thereof under the terms of any Permitted Bond Hedge Transaction or Permitted Warrant Transaction.

Each of the payments permitted by the foregoing Section 7.24(a) – (d) shall be referred to herein as "Permitted Convertible Debt Financing Payments").

7.25 Thermo Fisher Installment Payments. Notwithstanding anything to the contrary in this Agreement, Borrower may make the Thermo Fisher Installment Payments pursuant to any Thermo Fisher Agreement so long as (a) no Default or Event of Default has occurred and is continuing and (b) to the extent the Thermo Fisher Installment Payments constitute Indebtedness, such amounts are unsecured.

SECTION 8. RIGHT TO INVEST

8.1 Borrower shall provide (or in the case of a Subsequent Financing that is a registered offering, Borrower shall use its commercially reasonable efforts to request the managing underwriter(s) of such Subsequent Financing to provide) the Lenders or their permitted assignees or nominees, designated as such in writing to Borrower, the opportunity, in their discretion, to participate in any Subsequent Financing in an aggregate amount of up to the Five Million Dollars

($5,000,000) on the same terms, conditions and pricing afforded to others participating in any such Subsequent Financing, subject to compliance with all applicable securities laws and regulations. For the avoidance of doubt, in the event of a registered offering, to the extent Borrower has used its commercially reasonable efforts as set forth above and the managing underwriter(s) of a Subsequent Financing refuse to allocate securities to Lenders in accordance with the aforementioned request ("Underwriter Refusal"), Borrower shall have no further obligations or liability under this Section 8.1 with respect to such Subsequent Financing. If the Lenders (or their permitted assignees or nominees) elect to participate in any Subsequent Financing, the Lenders (or their permitted assignees or nominees, as applicable) participating in such Subsequent Financing agree to become a party to the agreements executed by the other investors participating in such Subsequent Financing, including with respect to obligations of confidentiality or as may otherwise be required by the Securities Act of 1933, as amended (the "Act"), and the rules and regulations promulgated by the Securities and Exchange Commission thereunder. Borrower, or an investment bank or underwriter engaged on Borrower's behalf, shall provide the Lenders or their permitted assignees or nominees at least one (1) Business Day's notice of any planned Subsequent Financing. This Section 8.1, and all rights and obligations provided for hereunder, shall terminate upon the earliest to occur of (a) termination of this Agreement, (b) such time that the Lenders or their assignees or nominees, have purchased Borrower's Equity Interests in an aggregate amount of at least Five Million Dollars ($5,000,000) in one or more Subsequent Financings and (c) Borrower extending (or causing to be extended) two (2) such offers to permit the Lenders or their permitted assignees or nominees the opportunity to participate in Subsequent Financings; provided that any Subsequent Financing resulting in an Underwriter Refusal shall not be included for purposes of achieving two (2) such offers.

SECTION 9. EVENTS OF DEFAULT

The occurrence of any one or more of the following events shall be an "Event of Default":

9.1 Payments. A Loan Party fails to pay any amount due under this Agreement or any of the other Loan Documents on the due date; provided, however, that an Event of Default shall not occur on account of a failure to pay due solely to an administrative or operational error of Agent or Lenders or Borrower's bank if Borrower had the funds to make the payment when due and makes the payment within three (3) Business Days following Borrower's knowledge of such failure to pay; or

9.2 Covenants. A Loan Party breaches or defaults in the performance of any covenant or Secured Obligation under this Agreement, or any of the other Loan Documents or any other agreement among Borrower, Agent and Lenders, and (a) with respect to a Default under any covenant under this Agreement (other than under Sections 4.5, 6, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9, 7.15, 7.17, 7.18, 7.19, 7.21, 7.22 ~~and~~, 7.24 and 7.25), any other Loan Document, or any other agreement among Borrower, Agent and Lenders, such default continues for more than twenty (20) days after the earlier of the date on which (i) Agent or Lenders has given notice of such default to Borrower and (ii) Borrower has actual knowledge of such default or (b) with respect to a Default under any of Sections 4.5, 6, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9, 7.15, 7.17, 7.18, 7.19, 7.21, 7.22 ~~and~~ 7.24 and 7.25), the occurrence of such Default; or

9.3 Material Adverse Effect. A circumstance has occurred that could reasonably be expected to have a Material Adverse Effect; provided that the occurrence of the following, individually, shall not, in and of itself, constitute a "Material Adverse Effect" hereunder: (i) the failure to achieve any Milestone, (ii) adverse results or delays with respect to, or the failure to achieve, any clinical or non-clinical trial goals or objectives, (iii) the denial, delay or limitation or

qualification of approval of the FDA or other regulatory agency with respect to any proposed drug or other Borrower Products, or (iv) any revisions to or termination of a strategic alliance, joint venture, co-promotion, co-commercialization or co-development agreements or license arrangement maintained by Borrower so long as the same does not affect the ability of Borrower to perform or pay the Secured Obligations in accordance with the terms of the Loan Documents; or

9.4 Representations. Any representation or warranty made by any Loan Party in any Loan Document shall have been false or misleading in any material respect when made or when deemed made; or

9.5 Insolvency. (a) A Loan Party or any of its Subsidiaries fails to be solvent as described under Section 5.15 hereof; (b) a Loan Party or any of its Subsidiaries begins an Insolvency Proceeding; or (c) an Insolvency Proceeding is begun against a Loan Party or any of its Subsidiaries and is not dismissed or stayed within forty-five (45) days (but no Advances shall be made while any of the conditions described in clause (a) exist or until any Insolvency Proceeding is dismissed); or

9.6 Judgments; Penalties. One or more fines, penalties or final judgments, orders or decrees for the payment of money in an amount, individually or in the aggregate, of at least [**] Dollars ($[**]) (not covered by independent third-party insurance as to which liability has been accepted by such insurance carrier) shall be rendered against any Loan Party or any of its Subsidiaries by any Governmental Authority, and the same are not, within twenty (20) days after the entry, assessment or issuance thereof, discharged, or after execution thereof, or stayed pending appeal, or such judgments are not discharged prior to the expiration of any such stay (provided that no Advances shall be made prior to the discharge, or stay of such fine, penalty, judgment, order or decree); or

9.7 Attachment; Levy; Restraint on Business.

(a) (i) The service of process seeking to attach, by trustee or similar process, any funds of any Loan Party or any of its Subsidiaries, or (ii) a notice of lien or levy is filed against any of any Loan Party's or any of its Subsidiaries' assets by any Governmental Authority, and the same under subclauses (i) and (ii) hereof are not, within twenty (20) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); provided, however, no Advances shall be made during any twenty (20) day cure period; or

(b) (i) any material portion of any Loan Party's or any of its Subsidiaries' assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents any Loan Party from conducting all or any material part of its business

9.8 Other Obligations. The occurrence of any default in which the Loan Party is the defaulting party under (i) any agreement or obligation of a Loan Party involving any Indebtedness in excess of [**] Dollars ($[**]), or (ii) any Material Agreement to the extent such default results in a right by a third party or parties, whether or not exercised, to terminate such Material Agreement or accelerate payments in excess of [**] Dollars ($[**]) owed thereunder.

SECTION 10. REMEDIES

10.1 General. Upon the occurrence and during the continuation of any one or more Events of Default, Agent may, and at the direction of the Required Lenders shall, accelerate and demand payment of all or any part of the outstanding Secured Obligations together with a Prepayment Charge and declare them to be immediately due and payable (provided, that upon the

occurrence of an Event of Default of the type described in Section 9.5, all of the Secured Obligations (including, without limitation, the Prepayment Charge and the End of Term Charge) shall automatically be accelerated and made due and payable, in each case without any further notice or act). Borrower hereby irrevocably appoints Agent as its lawful attorney-in-fact to: (a) exercisable following the occurrence and during the continuance of an Event of Default, (i) sign Borrower's name on any invoice or bill of lading for any account or drafts against account debtors; (ii) demand, collect, sue, and give releases to any account debtor for monies due, settle and adjust disputes and claims about the accounts directly with account debtors, and compromise, prosecute, or defend any action, claim, case, or proceeding about any Collateral (including filing a claim or voting a claim in any bankruptcy case in Agent's or Borrower's name, as Agent may elect); (iii) make, settle, and adjust all claims under Borrower's insurance policies; (iv) pay, contest or settle any Lien, charge, encumbrance, security interest, or other claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; (v) transfer the Collateral into the name of Agent or a third party as the UCC permits; (vi) receive, open and dispose of mail addressed to Borrower; (vii) endorse Borrower's name on any checks, payment instruments, or other forms of payment or security; and (viii) notify all account debtors to pay Agent directly. Borrower hereby appoints Agent as its lawful attorney-in-fact to sign Borrower's name on any documents necessary to perfect or continue the perfection of Agent's security interest in the Collateral regardless of whether an Event of Default has occurred until Payment in Full. Agent's foregoing appointment as Borrower's attorney in fact, and all of Agent's rights and powers, coupled with an interest, are irrevocable until Payment in Full. Agent may, and at the direction of the Required Lenders shall, exercise all rights and remedies with respect to the Collateral under the Loan Documents or otherwise available to it under the UCC and other applicable law, including the right to release, hold, sell, lease, liquidate, collect, realize upon, or otherwise dispose of all or any part of the Collateral and the right to occupy, utilize, process and commingle the Collateral. All Agent's rights and remedies shall be cumulative and not exclusive.

10.2 Collection; Foreclosure. Upon the occurrence and during the continuance of any Event of Default, Agent may, and at the direction of the Required Lenders shall, at any time or from time to time, apply, collect, liquidate, sell in one or more sales, lease or otherwise dispose of, any or all of the Collateral, in its then condition or following any commercially reasonable preparation or processing, in such order as Agent may elect. Any such sale may be made either at public or private sale at its place of business or elsewhere. Borrower agrees that any such public or private sale may occur upon ten (10) calendar days' prior written notice to Borrower. Agent may require Borrower to assemble the Collateral and make it available to Agent at a place designated by Agent that is reasonably convenient to Agent and Borrower. The proceeds of any sale, disposition or other realization upon all or any part of the Collateral shall be applied by Agent in the following order of priorities:

First, to Agent, in an amount equal to the sum of all fees owing to Agent hereunder and under any other Loan Document;

Second, to Agent and Lenders in an amount sufficient to pay in full Agent's and Lenders' reasonable costs and professionals' and advisors' fees and expenses as described in Section 11.12;

Third, to Lenders, ratably, in an amount equal to the sum of all accrued interest owing to Lenders on the Term Loan Advances hereunder;

Fourth, to Lenders, ratably, in an amount equal to the sum of the outstanding principal and premium, if any owing to Lenders from Borrower on the Term Loan Advances hereunder;

Fifth, to Lenders and Agent, ratably (in proportion to all remaining Secured Obligations owing to each), in an amount equal to the sum of all other outstanding and unpaid Secured Obligations (including principal, interest, and the default rate interest set forth in Section 2.4, if required under this Agreement), in such order and priority as Agent may choose in its sole discretion; and

Finally, after the full and final Payment in Full, to any creditor holding a junior Lien on the Collateral, or to Borrower or its representatives or as a court of competent jurisdiction may direct.

Agent shall be deemed to have acted reasonably in the custody, preservation and disposition of any of the Collateral if it complies with the obligations of a secured party under the UCC.

10.3 No Waiver. Agent shall be under no obligation to marshal any of the Collateral for the benefit of Borrower or any other Person, and Borrower expressly waives all rights, if any, to require Agent to marshal any Collateral.

10.4 Waivers. Borrower waives demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Agent on which Borrower is liable.

10.5 Cumulative Remedies. The rights, powers and remedies of Agent hereunder shall be in addition to all rights, powers and remedies given by statute or rule of law and are cumulative. The exercise of any one or more of the rights, powers and remedies provided herein shall not be construed as a waiver of or election of remedies with respect to any other rights, powers and remedies of Agent.

SECTION 11. MISCELLANEOUS

11.1 Severability. Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement shall be prohibited by or invalid under such law, such provision shall be ineffective only to the extent and duration of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Agreement.

11.2 Notice. Except as otherwise provided herein, any notice, demand, request, consent, approval, declaration, service of process or other communication (including the delivery of Financial Statements) that is required, contemplated, or permitted under the Loan Documents or with respect to the subject matter hereof shall be in writing, and shall be deemed to have been validly served, given, delivered, and received upon the earlier of: (i) the day of transmission by electronic mail or hand delivery or delivery by an overnight express service or overnight mail delivery service; or (ii) the third calendar day after deposit in the United States of America mails, with proper first class postage prepaid, in each case addressed to the party to be notified as follows:

(a) If to Agent:

HERCULES CAPITAL, INC.
Legal Department
Attention: Chief Legal Officer, [**]
1 North B Street, Suite 2000

San Mateo, CA 94401
email: [**]
Telephone: 650-289-3060

(b) If to Lenders:

HERCULES CAPITAL, INC.
Legal Department
Attention: Chief Legal Officer, [**]
1 North B Street, Suite 2000
San Mateo, CA 94401
email: [**]
Telephone: 650-289-3060

(c) If to Borrower:

DYNE THERAPEUTICS, INC.
Attention: Erick Lucera, Chief Financial Officer
1560 Trapelo Road
Waltham, MA 02451
email: [**]

With a copy (which shall not constitute notice) to:

WilmerHale
1225 Seventeenth St., Suite 2600
Denver, CO 80202 USA
Attn: Nathan J. Moore
Email: Nathan.Moore@Wilmerhale.com
Telephone: (720) 598-3462

or to such other address as each party may designate for itself by like notice.

11.3 Entire Agreement; Amendments.

(a) This Agreement and the other Loan Documents constitute the entire agreement and understanding of the parties hereto in respect of the subject matter hereof and thereof, and supersede and replace in their entirety any prior proposals, term sheets, non-disclosure or confidentiality agreements, letters, negotiations or other documents or agreements, whether written or oral, with respect to the subject matter hereof or thereof (including Agent's revised proposal letter dated [**] and the Non-Disclosure Agreement).

(b) Neither this Agreement, any other Loan Document, nor any terms hereof or thereof may be amended, supplemented or modified except in accordance with the provisions of this Section 11.3(b). The Required Lenders and Loan Parties party to the relevant Loan Document may, or, with the written consent of the Required Lenders, Agent and Loan Parties party to the relevant Loan Document may, from time to time, (i) enter into written amendments, supplements or modifications hereto and to the other Loan Documents for the purpose of adding any provisions to this Agreement or the other Loan Documents or changing in any manner the rights of Lenders or of Loan Parties hereunder or thereunder or (ii) waive, on such terms and conditions as the Required Lenders or Agent, as the case may be, may specify in such instrument, any of the requirements of

this Agreement or the other Loan Documents or any Default or Event of Default and its consequences; provided, however, that no such waiver and no such amendment, supplement or modification shall (A) forgive the principal amount or extend the final scheduled date of maturity of any Loan, extend the scheduled date of any amortization payment in respect of any Term Loan Advance, reduce the stated rate of any interest (or fee payable hereunder) or extend the scheduled date of any payment thereof, in each case without the written consent of each Lender directly affected thereby; (B) eliminate or reduce the voting rights of any Lender under this Section 11.3(b) without the written consent of such Lender; (C) reduce any percentage specified in the definition of Required Lenders, consent to the assignment or transfer by Loan Parties of any of its rights and obligations under this Agreement and the other Loan Documents, release all or substantially all of the Collateral or release a Loan Party from its obligations under the Loan Documents, in each case without the written consent of all Lenders; or (D) amend, modify or waive any provision of Section 11.18 or Addendum 4 without the written consent of Agent. Any such waiver and any such amendment, supplement or modification shall apply equally to each Lender and shall be binding upon the applicable Loan Parties, Lenders, Agent and all future holders of the Loans.

11.4 No Strict Construction. The parties hereto have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the parties hereto and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any provisions of this Agreement.

11.5 No Waiver. The powers conferred upon Agent and Lenders by this Agreement are solely to protect their rights hereunder and under the other Loan Documents and their interest in the Collateral and shall not impose any duty upon Agent or Lenders to exercise any such powers. No omission or delay by Agent or Lenders at any time to enforce any right or remedy reserved to them, or to require performance of any of the terms, covenants or provisions hereof by Borrower at any time designated, shall be a waiver of any such right or remedy to which Agent or Lenders are entitled, nor shall it in any way affect the right of Agent or Lenders to enforce such provisions thereafter.

11.6 Survival. All agreements, representations and warranties contained in this Agreement and the other Loan Documents or in any document delivered pursuant hereto or thereto shall be for the benefit of Agent and Lenders and shall survive the execution and delivery of this Agreement. Sections 6.3, 11.9, 11.11, 11.14, 11.15, 11.17 and 11.18 shall survive the termination of this Agreement.

11.7 Successors and Assigns. The provisions of this Agreement and the other Loan Documents shall inure to the benefit of and be binding on Borrower and its permitted assigns (if any). No Loan Party shall assign its obligations under this Agreement or any of the other Loan Documents without Agent's express prior written consent, and any such attempted assignment shall be void and of no effect. Agent and Lenders may not assign, transfer, or endorse its rights hereunder and under the other Loan Documents without the prior written consent of Borrower (not to be unreasonably withheld, conditioned or delayed); provided that no such consent shall be required for any such assignment, transfer or endorsement (x) after the occurrence of an Event of Default that is continuing, or (y) to Agent or a Lender or Affiliate of any Lender or Agent, and all of such rights shall inure to the benefit of Agent's and Lenders' successors and assigns. Notwithstanding the foregoing, (x) in connection with any assignment by a Lender as a result of a forced divestiture at the request of any regulatory agency, the restrictions set forth herein shall not apply and Agent and Lenders may assign, transfer or endorse its rights hereunder and under the other Loan Documents to any Person or party and (y) in connection with a Lender's own financing or securitization

transactions, the restrictions set forth herein shall not apply and Agent and Lenders may assign, transfer or endorse its rights hereunder and under the other Loan Documents to any Person or party providing such financing or formed to undertake such securitization transaction and any transferee of such Person or party upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; provided that no such sale, transfer, pledge or assignment under this clause (y) shall release such Lender from any of its obligations hereunder or substitute any such Person or party for such Lender as a party hereto until Agent shall have received and accepted an effective assignment agreement from such Person or party in form satisfactory to Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such assignee as Agent reasonably shall require. Agent, acting solely for this purpose as a non-fiduciary agent of Borrower, shall maintain at one of its offices in the United States a register for the recordation of the names and addresses of Lender(s), and the Term Commitments of, and principal amounts (and stated interest) of the Loans owing to, each Lender pursuant to the terms hereof from time to time (the "Register"). The entries in the Register shall be conclusive absent manifest error, and Borrower, Agent and Lender(s) shall treat each Person whose name is recorded in the Register pursuant to the terms hereof as a Lender hereunder for all purposes of this Agreement. The Register shall be available for inspection by Borrower and any Lender, at any reasonable time and from time to time upon reasonable prior notice.

11.8 Participations. Each Lender that sells a participation shall, acting solely for this purpose as a non-fiduciary agent of Borrower, maintain a register on which it enters the name and address of each participant and the principal amounts (and stated interest) of each participant's interest in the Loans or other obligations under the Loan Documents (the "Participant Register"); provided that no Lender shall have any obligation to disclose all or any portion of the Participant Register (including the identity of any participant or any information relating to a participant's interest in any commitments, loans, its other obligations under any Loan Document) to any Person except to the extent that such disclosure is necessary to establish that such commitment, loan, letter of credit or other obligation is in registered form under Section 5f.103-1(c) of the United States Treasury Regulations. The entries in the Participant Register shall be conclusive absent manifest error, and such Lender shall treat each Person whose name is recorded in the Participant Register as the owner of such participation for all purposes of this Agreement notwithstanding any notice to the contrary. For the avoidance of doubt, Agent (in its capacity as Agent) shall have no responsibility for maintaining a Participant Register. Borrower agrees that each participant shall be entitled to the benefits of the provisions in Addendum 1 attached hereto (subject to the requirements and limitations therein, including the requirements under Section 7 of Addendum 1 attached hereto (it being understood that the documentation required under Section 7 of Addendum 1 attached hereto shall be delivered to the participating Lender)) to the same extent as if it were a Lender and had acquired its interest by assignment pursuant to Section 11.7; provided that (A) such participant shall not be entitled to receive any greater payment under Addendum 1 attached hereto, with respect to any participation, than its participating Lender would have been entitled to receive, except to the extent such entitlement to receive a greater payment results from a change in law that occurs after the participant acquired the applicable participation, (B) each Lender agrees, at Borrower's request and expense, to use reasonable efforts to cooperate with Borrower to effectuate the provisions of Addendum 1 with respect to its participant(s), (C) no such participation shall release any Lender from any of its obligations under any Loan Document and (D) if no Event of Default has occurred and is continuing, no participant may be a direct competitor of Borrower (as reasonably determined by Agent).

11.9 Governing Law. This Agreement and the other Loan Documents have been negotiated and delivered to Agent and Lenders in the State of New York, and shall have been accepted by Agent and Lenders in the State of New York. Payment to Agent and Lenders by

Borrower of the Secured Obligations is due in the State of New York. This Agreement and the other Loan Documents shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, excluding conflict of laws principles that would cause the application of laws of any other jurisdiction.

11.10 Consent to Jurisdiction and Venue. All judicial proceedings (to the extent that the reference requirement of Section 11.11 is not applicable) arising in or under or related to this Agreement or any of the other Loan Documents may be brought in any state or federal court located in the State of New York. By execution and delivery of this Agreement, each party hereto generally and unconditionally: (a) consents to nonexclusive personal jurisdiction of the United States District Court for the Southern District of New York; (b) waives any objection as to jurisdiction or venue in the United States District Court for the Southern District of New York; (c) agrees not to assert any defense based on lack of jurisdiction or venue in the aforesaid courts; and (d) irrevocably agrees to be bound by any judgment rendered thereby in connection with this Agreement or the other Loan Documents. Service of process on any party hereto in any action arising out of or relating to this Agreement shall be effective if given in accordance with the requirements for notice set forth in Section 11.2, and shall be deemed effective and received as set forth in Section 11.2. Nothing herein shall affect the right to serve process in any other manner permitted by law or shall limit the right of either party to bring proceedings in the courts of any other jurisdiction.

11.11 Mutual Waiver of Jury Trial

. Because disputes arising in connection with complex financial transactions are most quickly and economically resolved by an experienced and expert Person and the parties wish applicable state and federal laws to apply (rather than arbitration rules), the parties desire that their disputes be resolved by a judge applying such applicable laws. EACH OF BORROWER, AGENT AND LENDERS SPECIFICALLY WAIVES ANY RIGHT IT MAY HAVE TO TRIAL BY JURY OF ANY CAUSE OF ACTION, CLAIM, CROSS-CLAIM, COUNTERCLAIM, THIRD PARTY CLAIM OR ANY OTHER CLAIM (COLLECTIVELY, "CLAIMS") ASSERTED BY BORROWER AGAINST AGENT, LENDERS OR THEIR RESPECTIVE ASSIGNEE OR BY AGENT, LENDERS OR THEIR RESPECTIVE ASSIGNEE AGAINST BORROWER. This waiver extends to all such Claims, including Claims that involve Persons other than Agent, Borrower or any Lenders; Claims that arise out of or are in any way connected to the relationship among Borrower, Agent and Lenders; and any Claims for damages, breach of contract, tort, specific performance, or any equitable or legal relief of any kind, arising out of this Agreement, any other Loan Document.

11.12 Professional Fees. Borrower promises to pay Agent's and Lenders' reasonable and documented out-of-pocket fees and expenses necessary to finalize the Loan Documents, including but not limited to reasonable and documented out-of-pocket attorneys' fees, UCC searches, filing costs, and other related expenses. In addition, Borrower promises to pay any and all reasonable and documented out-of-pocket attorneys' and other reasonable and documented out-of-pocket professionals' fees (excluding costs of in-house counsel) and reasonable and documented out-of-pocket expenses incurred by Agent and Lenders after the Closing Date in connection with or related to: (a) the Loan; (b) the administration, collection, or enforcement of the Loan; (c) the amendment or modification of the Loan Documents; (d) any waiver, consent, release, or termination under the Loan Documents; (e) the protection, preservation, audit, field exam, sale, lease, liquidation, or disposition of Collateral or the exercise of remedies with respect to the Collateral; (f) any legal, litigation, administrative, arbitration, or out of court proceeding in connection with or related to Borrower or the Collateral, and any appeal or review thereof; and (g) any bankruptcy, restructuring, reorganization, assignment for the benefit of creditors, workout, foreclosure, or other action related

to Borrower, the Collateral, the Loan Documents, including representing Agent or Lenders in any adversary proceeding or contested matter commenced or continued by or on behalf of Borrower's estate, and any appeal or review thereof.

11.13 Confidentiality. Agent and Lenders acknowledge that items of Collateral and information provided to Agent and Lenders by Borrower are confidential and proprietary information of Borrower, if and to the extent such information either (x) is marked as confidential by Borrower at the time of disclosure, or (y) should reasonably be understood to be confidential (the "Confidential Information"). Accordingly, Agent and Lenders agree that any Confidential Information it may obtain in connection with the Loan Documents or in the course of acquiring, administering, or perfecting Agent's security interest in the Collateral shall not be disclosed to any other Person or entity in any manner whatsoever, in whole or in part, without the prior written consent of Borrower, except that Agent and Lenders may disclose any such information: (a) to its Affiliates and its partners, investors, lenders, directors, officers, employees, agents, advisors, counsel, accountants, representatives and other professional advisors if Agent or Lenders in their sole discretion determine that any such party should have access to such information in connection with such party's responsibilities in connection with the Loan or this Agreement and, provided that such recipient of such Confidential Information either (i) agrees to be bound by the confidentiality provisions of this Section or (ii) is otherwise subject to confidentiality restrictions that reasonably protect against the disclosure of Confidential Information and in any case are not materially less restrictive than this Section; (b) if such information is generally available to the public or to the extent such information becomes publicly available other than as a result of a breach of this Section or becomes available to Agent or any Lender, or any of their respective Affiliates on a non-confidential basis from a source other than Borrower; (c) if required or appropriate in any report, statement or testimony required by law or order of any Governmental Authority to be submitted to any Governmental Authority having or claiming to have jurisdiction over Agent or Lenders and any rating agency; (d) if required or appropriate in response to any summons or subpoena or in connection with any litigation, to the extent permitted or deemed advisable by Agent's or Lenders' counsel; (e) to comply with any legal requirement or law applicable to Agent or Lenders or demanded by any Governmental Authority; (f) to the extent reasonably necessary in connection with the exercise of, or preparing to exercise, or the enforcement of, or preparing to enforce, any right or remedy under any Loan Document (including Agent's sale, lease, or other disposition of Collateral after the occurrence and during the continuance of an Event of Default), or any action or proceeding relating to any Loan Document; (g) to any participant or assignee of Agent or Lenders or any bona fide prospective participant or assignee, provided, that such participant or assignee or prospective participant or assignee is subject to confidentiality restrictions that reasonably protect against the disclosure of Confidential Information which are not materially less restrictive than this Section; (h) to any investor or bona fide potential investor (and each of their respective Affiliates or clients) in Agent or Lenders (or each of their respective Affiliates); provided that such investor, potential investor, Affiliate or client is subject to confidentiality obligations with respect to the Confidential Information which are not materially less restrictive than this Section; (i) otherwise to the extent consisting of general portfolio information that does not identify Borrower; or (j) otherwise with the prior written consent of Borrower; provided, that any disclosure made in violation of this Agreement shall not affect the obligations of Borrower or any of its Affiliates or any guarantor under this Agreement or the other Loan Documents. Agent's and Lenders' obligations under this Section 11.13 shall supersede all of their respective obligations under the Non-Disclosure Agreement.

11.14 Assignment of Rights. Borrower acknowledges and understands that Agent or Lenders may, subject to Section 11.7, sell and assign all or part of its interest hereunder and under the Loan Documents to any Person or entity (an "Assignee"). After such assignment the term "Agent" or "Lender" as used in the Loan Documents shall mean and include such Assignee, and

such Assignee shall be vested with all rights, powers and remedies of Agent and Lenders hereunder with respect to the interest so assigned; but with respect to any such interest not so transferred, Agent and Lenders shall retain all rights, powers and remedies hereby given. No such assignment by Agent or Lenders shall relieve Borrower of any of its obligations hereunder. Lenders agree that in the event of any transfer by it of the promissory note(s) (if any), it will endorse thereon a notation as to the portion of the principal of the promissory note(s), which shall have been paid at the time of such transfer and as to the date to which interest shall have been last paid thereon.

11.15 Revival of Secured Obligations. This Agreement and the Loan Documents shall remain in full force and effect and continue to be effective if any petition is filed by or against Borrower for liquidation or reorganization, if Borrower becomes insolvent or makes an assignment for the benefit of creditors, if a receiver or trustee is appointed for all or any significant part of Borrower's assets, or if any payment or transfer of Collateral is recovered from Agent or Lenders. The Loan Documents and the Secured Obligations and Collateral security shall continue to be effective, or shall be revived or reinstated, as the case may be, if at any time payment and performance of the Secured Obligations or any transfer of Collateral to Agent, or any part thereof is rescinded, avoided or avoidable, reduced in amount, or must otherwise be restored or returned by, or is recovered from, Agent, Lenders or by any obligee of the Secured Obligations, whether as a "voidable preference," "fraudulent conveyance," or otherwise, all as though such payment, performance, or transfer of Collateral had not been made. In the event that any payment, or any part thereof, is rescinded, reduced, avoided, avoidable, restored, returned, or recovered, the Loan Documents and the Secured Obligations shall be deemed, without any further action or documentation, to have been revived and reinstated except to the extent of the full, final, and indefeasible payment to Agent or Lenders in Cash.

11.16 Counterparts. This Agreement and any amendments, waivers, consents or supplements hereto may be executed in any number of counterparts, and by different parties hereto in separate counterparts, each of which when so delivered shall be deemed an original, but all of which counterparts shall constitute but one and the same instrument.

11.17 No Third-Party Beneficiaries. No provisions of the Loan Documents are intended, nor will be interpreted, to provide or create any third-party beneficiary rights or any other rights of any kind in any Person other than Agent, Lenders and Borrower unless specifically provided otherwise herein, and, except as otherwise so provided, all provisions of the Loan Documents will be personal and solely among Agent, Lenders and the Loan Parties party thereto.

11.18 Agency. Agent and each Lender hereby agree to the terms and conditions set forth on Addendum 4 attached hereto. Borrower acknowledges and agrees to the terms and conditions set forth on Addendum 4 attached hereto.

11.19 Publicity. None of the parties hereto nor any of its respective member businesses and Affiliates shall, without the other parties' prior written consent (which shall not be unreasonably withheld or delayed), publicize or use (a) the other party's name (including a brief description of the relationship among the parties hereto), logo or hyperlink to such other parties' web site, separately or together, in written and oral presentations, advertising, promotional and marketing materials, client lists, public relations materials or on its web site (together, the "Publicity Materials"); (b) the names of officers of such other parties in the Publicity Materials; and (c) such other parties' name, trademarks, servicemarks in any news or press release concerning such party; provided however, notwithstanding anything to the contrary herein, no consent shall be required to disclose information (i) to the extent necessary to comply with the requests of any regulators, legal requirements or laws applicable to such party, pursuant to any listing agreement with any national securities exchange or

the rules and regulations of the Securities and Exchange Commission (so long as such party provides prior notice to the other party hereto to the extent reasonably practicable) and (ii) to comply with Section 11.13.

11.20 Multiple Borrowers. Each Borrower hereby agrees to the terms and conditions set forth on Addendum 5 attached hereto.

11.21 Managerial Assistance. Borrower acknowledges that Hercules Capital, Inc. has elected to be regulated as a business development company under the 1940 Act, and as such is required to make available significant managerial assistance to its portfolio companies. Significant managerial assistance may include, but is not limited to, guidance and counsel concerning the portfolio company's management, operations, business objectives and policies, arrangement of financing, management of relationships with financing sources, recruitment of management personnel and evaluation of acquisition and divestiture opportunities. Borrower hereby acknowledges and agrees that it may request such assistance at any time from Hercules Capital, Inc. by contacting [**].

11.22 Electronic Execution of Certain Other Documents. The words "execution," "execute", "signed," "signature," and words of like import in or related to any document to be signed in connection with this Agreement and the transactions contemplated hereby (including without limitation assignments, assumptions, amendments, waivers and consents) shall be deemed to include electronic signatures, the electronic matching of assignment terms and contract formations on electronic platforms approved by Agent, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

(SIGNATURES TO FOLLOW)

IN WITNESS WHEREOF, Borrower, Agent and Lenders have duly executed and delivered this Loan and Security Agreement as of the day and year first above written.

BORROWER:

DYNE THERAPEUTICS, INC.

Signature: /s/ Erick Lucera_____

Print Name: Erick Lucera

Title: Chief Financial Officer and Treasurer

Accepted in San Mateo, California:

AGENT:

HERCULES CAPITAL, INC.

Signature:/s/ Seth Meyer_____

Print Name: Seth Meyer

Title: Chief Financial Officer

LENDERS:

HERCULES CAPITAL, INC.

Signature:/s/ Seth Meyer_____

Print Name: Seth Meyer

Title: Chief Financial Officer

HERCULES PRIVATE CREDIT FUND 1 L.P.

By: Hercules ~~Adviser~~Private Global Venture Growth Fund GP I LLC, its ~~Investment Adviser~~General Partner

Signature:/s/ Seth Meyer_____

Print Name: Seth Meyer

Title: Authorized Signatory

HERCULES PRIVATE GLOBAL VENTURE

GROWTH FUND I L.P.

By: Hercules ~~Adviser~~Private Global Venture Growth Fund GP I LLC, its ~~Investment Adviser~~General Partner

Signature:/s/ Seth Meyer_____

Print Name: Seth Meyer

Title: Authorized Signatory

HERCULES VENTURE GROWTH CREDIT

OPPORTUNITIES FUND I L.P.

By: Hercules ~~Adviser~~Venture Growth Credit Opportunities Fund GP I LLC, its ~~Investment Adviser~~General Partner

Signature:/s/ Seth Meyer_____

Print Name: Seth Meyer

Title: Authorized Signatory

HERCULES CAPITAL IV, L.P.

By: Hercules Technology SBIC

Management, LLC, its General Partner

By: Hercules Capital, Inc., its Manager

Signature:/s/ Seth Meyer_____

Print Name: Seth Meyer

Title: Chief Financial Officer

HERCULES SBIC V, L.P.

By: Hercules Technology SBIC

Management, LLC, its General Partner

By: Hercules Capital, Inc., its Manager

Signature:/s/ Seth Meyer_____

Print Name: Seth Meyer

Title: Chief Financial Officer

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ADDENDUM 1 to LOAN AND SECURITY AGREEMENT

TAXES; INCREASED COSTS

1. **Defined Terms**. For purposes of this Addendum 1:

a. "**Connection Income Taxes**" means Other Connection Taxes that are imposed on or measured by net income (however denominated) or that are franchise Taxes or branch profits Taxes.

b. "**Excluded Taxes**" means any of the following Taxes imposed on or with respect to a Recipient or required to be withheld or deducted from a payment to a Recipient, (i) Taxes imposed on or measured by net income (however denominated), franchise Taxes, and branch profits Taxes, in each case, (A) imposed as a result of such Recipient being organized under the laws of, or having its principal office or, in the case of any Lender, its applicable lending office located in, the jurisdiction imposing such Tax (or any political subdivision thereof) or (B) that are Other Connection Taxes, (ii) in the case of a Lender, U.S. federal withholding Taxes imposed on amounts payable to or for the account of such Lender with respect to an applicable interest in a Loan or Term Commitment pursuant to a law in effect on the date on which (A) such Lender acquires such interest in the Loan or Term Commitment or (B) such Lender changes its lending office, except in each case to the extent that, pursuant to Section 2 or Section 4 of this Addendum 1, amounts with respect to such Taxes were payable either to such Lender's assignor immediately before such Lender became a party hereto or to such Lender immediately before it changed its lending office, (iii) Taxes attributable to such Recipient's failure to comply with Section 7 of this Addendum 1 and (iv) any withholding Taxes imposed under FATCA.

c. "**FATCA**" means Sections 1471 through 1474 of the Code, as of the date of this Agreement (or any amended or successor version that is substantively comparable and not materially more onerous to comply with), any current or future regulations or official interpretations thereof, any agreements entered into pursuant to Section 1471(b)(1) of the Code, and any fiscal or regulatory legislation, rules or practices adopted pursuant to any intergovernmental agreement, treaty or convention among Governmental Authorities and implementing such Sections of the Code.

d. "**Foreign Lender**" means a Lender that is not a U.S. Person.

e. "**Indemnified Taxes**" means (i) Taxes, other than Excluded Taxes, imposed on or with respect to any payment made by or on account of any obligation of Borrower under any Loan Document and (ii) to the extent not otherwise described in clause (i), Other Taxes.

f. "**Other Connection Taxes**" means, with respect to any Recipient, Taxes imposed as a result of a present or former connection between such Recipient and the jurisdiction imposing such Tax (other than connections arising from such Recipient having executed, delivered, become a party to, performed its obligations under, received payments under, received or perfected a security interest under, engaged in any other transaction pursuant to or enforced any Loan Document, or sold or assigned an interest in any Loan or Loan Document).

g. "**Other Taxes**" means all present or future stamp, court or documentary, intangible, recording, filing or similar Taxes that arise from any payment made under, from the execution, delivery, performance, enforcement or registration of, from the receipt or perfection of a security interest under, or otherwise with respect to, any Loan Document, except any such Taxes that are Other Connection Taxes imposed with respect to an assignment.

h. "**Recipient**" means Agent or any Lender, as applicable.

i. "**Withholding Agent**" means Borrower and Agent.

2. **Payments Free of Taxes**. Any and all payments by or on account of any obligation of Borrower under any Loan Document shall be made without deduction or withholding for any Taxes, except as required by applicable law. If any applicable law (as determined in the good faith discretion of an applicable Withholding Agent) requires the deduction or withholding of any Tax from any such payment by a Withholding Agent, then the applicable Withholding Agent shall be entitled to make such deduction or withholding and shall timely pay the full amount deducted or withheld to the relevant Governmental Authority in accordance with applicable law and, if such Tax is an Indemnified Tax, then the sum payable by Borrower shall be increased as necessary so that after such deduction or withholding has been made (including such deductions and withholdings applicable to additional sums payable under this Section 2 or Section 4 of this Addendum 1) the applicable Recipient receives an amount equal to the sum it would have received had no such deduction or withholding been made.

3. **Payment of Other Taxes by Borrower**. Borrower shall timely pay to the relevant Governmental Authority in accordance with applicable law, or at the option of Agent timely reimburse it for the payment of, any Other Taxes.

4. **Indemnification by Borrower**. Borrower shall indemnify each Recipient, within ten (10) days after demand therefor, for the full amount of any Indemnified Taxes (including Indemnified Taxes imposed or asserted on or attributable to amounts payable under Section 2 of this Addendum 1 or this Section 4) payable or paid by such Recipient or required to be withheld or deducted from a payment to such Recipient and any reasonable expenses arising therefrom or with respect thereto, whether or not such Indemnified Taxes were correctly or legally imposed or asserted by the relevant Governmental Authority. A certificate describing the amount of such payment or liability delivered to Borrower by a Lender (with a copy to Agent), or by Agent on its own behalf or on behalf of a Lender, shall be conclusive absent manifest error. In addition, Borrower agrees to pay, and to hold Agent and any Lender harmless from, any and all liabilities with respect to, or resulting from any delay in paying, any and all excise, sales or other similar Taxes (excluding Taxes imposed on or measured by the net income of Agent or such Lender) that may be payable or determined to be payable with respect to any of the Collateral or this Agreement.

5. **Indemnification by Lenders**. Each Lender shall severally indemnify Agent, within ten (10) days after demand therefor, for (a) any Indemnified Taxes attributable to such Lender (but only to the extent that Borrower has not already indemnified Agent for such Indemnified Taxes and without limiting the obligation of Borrower to do so), (b) any Taxes attributable to such Lender's failure to comply with the provisions of

Section 11.8 of the Agreement relating to the maintenance of a Participant Register and (c) any Excluded Taxes attributable to such Lender, in each case, that are payable or paid by Agent in connection with any Loan Document, and any reasonable expenses arising therefrom or with respect thereto, whether or not such Taxes were correctly or legally imposed or asserted by the relevant Governmental Authority. A certificate as to the amount of such payment or liability delivered to any Lender by Agent shall be conclusive absent manifest error. Each Lender hereby authorizes Agent to set off and apply any and all amounts at any time owing to such Lender under any Loan Document or otherwise payable by Agent to Lenders from any other source against any amount due to Agent under this Section 5.

6. **Evidence of Payments**. As soon as practicable after any payment of Taxes by Borrower to a Governmental Authority pursuant to the provisions of this Addendum 1, Borrower shall deliver to Agent the original or a certified copy of a receipt issued by such Governmental Authority evidencing such payment, a copy of the return reporting such payment or other evidence of such payment reasonably satisfactory to Agent.

7. **Status of Lenders**.

a. Any Lender that is entitled to an exemption from or reduction of withholding Tax with respect to payments made under any Loan Document shall deliver to Borrower and Agent, at the time or times reasonably requested by Borrower or Agent, such properly completed and executed documentation reasonably requested by Borrower or Agent as will permit such payments to be made without withholding or at a reduced rate of withholding. In addition, any Lender, if reasonably requested by Borrower or Agent, shall deliver such other documentation prescribed by applicable law or reasonably requested by Borrower or Agent as will enable Borrower or Agent to determine whether or not such Lender is subject to backup withholding or information reporting requirements. Notwithstanding anything to the contrary in the preceding two sentences, the completion, execution and submission of such documentation (other than such documentation set forth in Sections 7(b)(i), 7(b)(ii) and 7(b)(iv) of this Addendum 1) shall not be required if in such Lender's reasonable judgment such completion, execution or submission would subject such Lender to any material unreimbursed cost or expense or would materially prejudice the legal or commercial position of such Lender.

b. Without limiting the generality of the foregoing, in the event that Borrower is a U.S. Person,

i. any Lender that is a U.S. Person shall deliver to Borrower and Agent on or prior to the date on which such Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of Borrower or Agent), executed copies of IRS Form W-9 certifying that such Lender is exempt from U.S. federal backup withholding tax;

ii. any Foreign Lender shall, to the extent it is legally entitled to do so, deliver to Borrower and Agent (in such number of copies as shall be requested by the recipient) on or prior to the date on which such Foreign Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of Borrower or Agent), whichever of the following is applicable:

A. in the case of a Foreign Lender claiming the benefits of an income tax treaty to which the United States is a party (x) with respect to payments of interest under any Loan Document, executed copies of IRS Form W-8BEN or IRS Form W-8BEN-E establishing an exemption from, or reduction of, U.S. federal withholding Tax pursuant to the "interest" article of such tax treaty and (y) with respect to any other applicable payments under any Loan Document, IRS Form W-8BEN or IRS Form W-8BEN-E establishing an exemption from, or reduction of, U.S. federal withholding Tax pursuant to the "business profits" or "other income" article of such tax treaty;

B. executed copies of IRS Form W-8ECI;

C. in the case of a Foreign Lender claiming the benefits of the exemption for portfolio interest under Section 881(c) of the Code, (x) a certificate substantially in the form of Exhibit J-1 to the effect that such Foreign Lender is not a "bank" within the meaning of Section 881(c)(3)(A) of the Code, a "10 percent shareholder" of Borrower within the meaning of Section 871(h)(3)(B) of the Code, or a "controlled foreign corporation" related to Borrower as described in Section 881(c)(3)(C) of the Code (a "U.S. Tax Compliance Certificate") and (y) executed copies of IRS Form W-8BEN or IRS Form W-8BEN-E; or

D. to the extent a Foreign Lender is not the beneficial owner, executed copies of IRS Form W-8IMY, accompanied by IRS Form W-8ECI, IRS Form W-8BEN, IRS Form W-8BEN-E, a U.S. Tax Compliance Certificate substantially in the form of Exhibit J-2 or Exhibit J-3, IRS Form W-9, and/or other certification documents from each beneficial owner, as applicable; provided that if the Foreign Lender is a partnership and one or more direct or indirect partners of such Foreign Lender are claiming the portfolio interest exemption, such Foreign Lender may provide a U.S. Tax Compliance Certificate substantially in the form of Exhibit J-4 on behalf of each such direct and indirect partner;

iii. any Foreign Lender shall, to the extent it is legally entitled to do so, deliver to Borrower and Agent (in such number of copies as shall be requested by the recipient) on or prior to the date on which such Foreign Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of Borrower or Agent), executed copies of any other form prescribed by applicable law as a basis for claiming exemption from or a reduction in U.S. federal withholding Tax, duly completed, together with such supplementary documentation as may be prescribed by applicable law to permit Borrower or Agent to determine the withholding or deduction required to be made; and

iv. if a payment made to a Lender under any Loan Document would be subject to U.S. federal withholding Tax imposed by FATCA if such Lender were to fail to comply with the applicable reporting requirements of FATCA (including those contained in Section 1471(b) or 1472(b) of the Code, as applicable), such Lender shall deliver to Borrower and Agent at the time or times prescribed by law and at such time or times reasonably requested by Borrower or Agent such documentation prescribed by applicable law (including as prescribed by Section 1471(b)(3)(C)(i) of the Code) and such additional documentation reasonably requested by Borrower or Agent as may be necessary for Borrower and Agent to comply with their obligations under FATCA and to determine that such Lender has complied with such Lender's obligations under FATCA or to determine the amount, if any, to deduct and withhold from such payment. Solely for purposes of this clause (iv), "FATCA" shall include any amendments made to FATCA after the date of this Agreement.

c. Each Lender agrees that if any form or certification it previously delivered expires or becomes obsolete or inaccurate in any respect, it shall update such form or certification or promptly notify Borrower and Agent in writing of its legal inability to do so.

8. **Treatment of Certain Refunds**. If any party determines, in its sole discretion exercised in good faith, that it has received a refund of any Taxes as to which it has been indemnified pursuant to the provisions of this Addendum 1 (including by the payment of additional amounts pursuant to the provisions of this Addendum 1), it shall pay to the indemnifying party an amount equal to such refund (but only to the extent of indemnity payments made under the provisions of this Addendum 1 with respect to the Taxes giving rise to such refund), net of all out-of-pocket expenses (including Taxes) of such indemnified party and without interest (other than any interest paid by the relevant Governmental Authority with respect to such refund). Such indemnifying party, upon the request of such indemnified party, shall repay to such indemnified party the amount paid over pursuant to this Section 8 (plus any penalties, interest or other charges imposed by the relevant Governmental Authority) in the event that such indemnified party is required to repay such refund to such Governmental Authority. Notwithstanding anything to the contrary in this Section 8, in no event will the indemnified party be required to pay any amount to an indemnifying party pursuant to this Section 8 the payment of which would place the indemnified party in a less favorable net after-Tax position than the indemnified party would have been in if the Tax subject to indemnification and giving rise to such refund had not been deducted, withheld or otherwise imposed and the indemnification payments or additional amounts with respect to such Tax had never been paid. This Section 8 shall not be construed to require any indemnified party to make available its Tax returns (or any other information relating to its Taxes that it deems confidential) to the indemnifying party or any other Person.

9. **Increased Costs**. If any change in applicable law shall subject any Recipient to any Taxes (other than (A) Indemnified Taxes, (B) Taxes described in clauses (ii) through (iv) of the definition of Excluded Taxes and (C) Connection Income Taxes) on its loans, loan principal, commitments, or other obligations, or its deposits, reserves, other liabilities or capital attributable thereto, and the result shall be to increase the cost to such Recipient of making, converting to, continuing or maintaining any Term Loan Advance or of maintaining its obligation to make any such Loan, or to reduce the amount of any sum received or receivable by such Recipient (whether of principal, interest or any other amount), then, upon the request of such Recipient, Borrower will pay to such Recipient such additional amount or amounts as will compensate such Recipient for such additional costs incurred or reduction suffered.

10. **Survival**. Each party's obligations under the provisions of this Addendum 1 shall survive the resignation or replacement of Agent or any assignment of rights by, or the replacement of, a Lender, the termination of the Term Commitments and the repayment, satisfaction or discharge of all obligations under any Loan Document.

ADDENDUM 2 to LOAN AND SECURITY AGREEMENT

Delivery Instructions

The Compliance Certificate shall be uploaded and executed via Lumonic[1]. All other financial reports required to be furnished to Agent pursuant to Section 7.1 shall be submitted via Lumonic.

The Compliance Certificate and other financial reports required to be furnished to Agent pursuant to Section 7.1 may be sent to [**] with a copy to [**], should access to Lumonic be temporarily unavailable.

[1] All references to Lumonic shall be interpreted as the Portfolio Management Software currently in use by Agent. Lumonic can be reached at the following URL: https://lumonic.com/

ADDENDUM 3 to LOAN AND SECURITY AGREEMENT

SBIC

(a) *Borrower's Business*. For purposes of this Addendum 3, Borrower shall be deemed to include its "affiliates" as defined in Title 13 Code of Federal Regulations Section 121.103. Borrower (i) represents and warrants to Agent and Lenders, with respect to subsection 1 below, as of the initial SBA Funding Date, and (ii) represents and warrants to Agent and Lenders, as of each SBA Funding Date and covenants to Agent and Lenders for a period of one year after each SBA Funding Date or for such longer period as set forth below with respect to subsections 2, 3, 4, 5, 6 and 7 below, as follows:

1. Size Status. Borrower's primary NAICS code is 541714 and has less than 250 employees in the aggregate (as determined in accordance with Title 13 Code of Federal Regulations Section 121.106);

2. No Relender. Borrower's primary business activity does not involve, directly or indirectly, providing funds to others, purchasing debt obligations, factoring, or long-term leasing of equipment with no provision for maintenance or repair;

3. No Passive Business. Borrower is engaged in a regular and continuous business operation (excluding the mere receipt of payments such as dividends, rents, lease payments, or royalties). Borrower's employees are carrying on the majority of day to day operations. Borrower will not pass through substantially all of the proceeds of the Loan to another entity;

4. No Real Estate Business. Borrower is not classified under North American Industry Classification System (NAICS) codes 531110 (lessors of residential buildings and dwellings), 531120 (lessors of nonresidential buildings except miniwarehouses), 531190 (lessors of other real estate property), 237210 (land subdivision), or 236117 (new housing for-sale builders). Borrower is not classified under NAICS codes 236118 (residential remodelers), 236210 (industrial building construction), or 236220 (commercial and institutional building construction), if Borrower is primarily engaged in construction or renovation of properties on its own account rather than as a hired contractor. Borrower is not classified under NAICS codes 531210 (offices of real estate agents and brokers), 531311 (residential property managers), 531312 (nonresidential property managers), 531320 (offices of real estate appraisers), or 531390 (other activities related to real estate), unless it derives at least 80 percent of its revenue from non-Affiliate sources. The proceeds of the Loan will not be used to acquire or refinance real property unless Borrower (x) is acquiring an existing property and will use at least 51 percent of the usable square footage for its business purposes; (y) is building or renovating a building and will use at least 67 percent of the usable square footage for its business purposes; or (z) occupies the subject property and uses at least 67 percent of the usable square footage for its business purposes.

5. No Project Finance. Borrower's assets are not intended to be reduced or consumed, generally without replacement, as the life of its business

progresses, and the nature of Borrower's business does not require that a stream of cash payments be made to the business's financing sources, on a basis associated with the continuing sale of assets (e.g., real estate development projects and oil and gas wells). The primary purpose of the Loan is not to fund production of a single item or defined limited number of items, generally over a defined production period, where such production will constitute the majority of the activities of Borrower (e.g., motion pictures and electric generating plants).

6. No Farm Land Purchases. Borrower will not use the proceeds of the Loan to acquire farm land which is or is intended to be used for agricultural or forestry purposes, such as the production of food, fiber, or wood, or is so taxed or zoned.

7. No Foreign Investment. The proceeds of the Loan will not be used substantially for a foreign operation, passed through to a foreign business or used to acquire a foreign business. Borrower will not have, on or within one year after each SBA Funding Date and each other Loan provided by a Lender that is an SBIC more than 49 percent of its employees or tangible assets located outside the United States of America.

(b) *Small Business Administration Documentation*. Agent and Lenders acknowledge that Borrower completed, executed and delivered to Agent prior to each SBA Funding Date SBA Forms 480, 652 and 1031 (Parts A and B) together with a business plan showing Borrower's financial projections (including balance sheets and income and cash flows statements) for the period described therein and a written statement (whether included in the purchase agreement or pursuant to a separate statement) from Agent regarding its intended use of proceeds from the sale of securities to Lenders (the "Use of Proceeds Statement"). Borrower represents and warrants to Agent and Lenders that the information regarding Borrower and its affiliates set forth in the SBA Form 480, Form 652 and Form 1031 and the Use of Proceeds Statement delivered as of each SBA Funding Date is accurate and complete.

(c) *Inspection*. The following covenants contained in this Section (c) are intended to supplement and not to restrict the related provisions of the Loan Documents. Subject to the preceding sentence, Borrower will permit, for so long as Lenders hold any debt or equity securities of Borrower, Agent, Lenders or their representative, at Agent's or Lenders' expense, and examiners of the SBA to visit and inspect the properties and assets of Borrower, to examine its books of account and records, and to discuss Borrower's affairs, finances and accounts with Borrower's officers, senior management and accountants, all at such reasonable times as may be requested by Agent or Lenders or the SBA.

(d) *Annual Assessment*. Upon request of Agent or Lender, promptly after the end of each calendar year (but in any event prior to February 28 of each year) and at such other times as may be reasonably requested by Agent or Lenders, Borrower will deliver to Agent a written assessment of the economic impact of Lenders' investment in Borrower, specifying the full-time equivalent net jobs created and total jobs created or retained in connection with the investment, the impact of the investment on the revenues and profits of Borrower's business and on taxes paid by Borrower and its employees, and such other information as may be required regarding Borrower in connection with the filing of Lenders' SBA Form 468. Lenders will assist Borrower with preparing such assessment. In addition to any other rights granted hereunder, Borrower will grant Agent and Lenders and the SBA access to Borrower's books and records for the purpose of verifying the use

of such proceeds. Borrower also will furnish or cause to be furnished to Agent and Lenders such other information regarding the business, affairs and condition of Borrower as Agent or Lenders may from time to time reasonably request, and such information shall be certified by the President, Chief Executive Officer or Chief Financial Officer of Borrower to the extent requested by Agent or Lender for compliance with the SBIC Act.

(e) *Use of Proceeds.* Borrower will use the proceeds from the Loan only for purposes set forth in Section 7.17. Borrower will deliver to Agent from time to time promptly following Agent's request, a written report, certified as correct by Borrower's Chief Financial Officer, verifying the purposes and amounts for which proceeds from the Loan have been disbursed. Borrower will supply to Agent such additional information and documents as Agent reasonably requests with respect to its use of proceeds and will permit Agent and Lenders and the SBA to have access to any and all Borrower records and information and personnel as Agent deems necessary to verify how such proceeds have been or are being used, and to assure that the proceeds have been used for the purposes specified in Section 7.17.

(f) *Activities and Proceeds*. Neither Borrower nor any of its affiliates (if any) will engage in any activities or use directly or indirectly the proceeds from the Loan for any purpose for which a small business investment company is prohibited from providing funds by the SBIC Act, including 13 C.F.R. §107.720. Borrower shall not, nor shall it cause or permit any of its subsidiaries to, without obtaining the prior written approval of Agent, change Borrower's or any such subsidiary's business activities from that conducted on the date hereof to a business activity from which a licensee under the SBIC Act is prohibited from providing funds by the SBIC Act. Borrower agrees that any such change in its or any such subsidiary's business activities without such prior written consent of Agent shall constitute a material breach of the obligations of Borrower under this Addendum 3.

(g) *Compliance and Resolution.* Borrower agrees that a failure to comply with Borrower's obligations under this Addendum, or any other set of facts or circumstances where it has been asserted by any governmental regulatory agency (or Agent or Lenders believes that there is a substantial risk of such assertion) that Agent, Lenders and their affiliates are not entitled to hold, or exercise any significant right with respect to, any securities issued to Lenders by Borrower, will constitute a breach of the obligations of Borrower under the financing agreements among Borrower, Agent and Lenders. In the event of (i) a failure to comply with Borrower's obligations under this Addendum; or (ii) an assertion by any governmental regulatory agency (or Agent or Lenders believe that there is a substantial risk of such assertion) of a failure to comply with Borrower's obligations under this Addendum, then (i) Agent, Lenders and Borrower will meet and resolve any such issue in good faith to the satisfaction of Borrower, Agent, Lenders, and any governmental regulatory agency, and (ii) upon request of Lenders or Agent, Borrower will cooperate and assist with any assignment of the financing agreements among Hercules Capital IV, L.P. and Hercules SBIC V, L.P., as applicable, and Hercules Capital, Inc.

ADDENDUM 4 to LOAN AND SECURITY AGREEMENT

Agent and Lender Terms

(a) Each Lender hereby irrevocably appoints Hercules Capital, Inc. to act on its behalf as Agent hereunder and under the other Loan Documents and irrevocably authorizes Agent to take such actions on its behalf and to exercise such powers as are delegated to Agent by the terms hereof or thereof, together with such actions and powers as are reasonably incidental thereto. Agent shall have only those duties which are specified in this Agreement and it may perform such duties by or through its agents, representatives or employees. In performing its duties on behalf of Lenders, Agent shall exercise the same care which it would exercise in dealing with loans made for its own account, but it shall not be responsible to any Lender for the execution, effectiveness, genuineness, validity, enforceability, collectability or sufficiency of all or any of the Loan Documents, or for any representations, warranties, recitals or statements made therein or made in any written or oral statement or in any financial or other statements, instruments, reports, certificates or any other documents furnished or delivered in connection herewith or therewith by Agent to any Lender or by or on behalf of Borrower to Agent or any Lender, or be required to ascertain or inquire as to the performance or observance of any of the terms, conditions, provisions, covenants or agreements contained herein or therein, as to the use of the proceeds of the Term Loan Advances, the contents of any certificate, report or other document delivered hereunder or thereunder or in connection herewith or therewith, the validity, enforceability, effectiveness or genuineness of this Agreement, any other Loan Document or any other agreement, instrument or document or the satisfaction of any condition set forth in Section 4 or elsewhere herein, other than to confirm receipt of items expressly required to be delivered to Agent. Agent shall not be responsible for insuring the Collateral or for the payment of any Taxes, assessments, charges or any other charges or liens of any nature whatsoever upon the Collateral or otherwise for the maintenance of the Collateral, except in the event Agent enters into possession of a part or all of the Collateral, in which event Agent shall preserve the part in its possession. Unless the officers of Agent acting in their capacity as officer of Agent on Borrower's account have actual knowledge thereof or have been notified in writing thereof by Lenders, Agent shall not be required to ascertain or inquire as to the existence or possible existence of any Event of Default.

(b) Neither Agent nor any of its officers, directors, employees, attorneys, representatives or agents shall be liable to Lenders for any action taken or omitted hereunder or under any of the other Loan Documents or in connection herewith or therewith unless caused by its or their gross negligence or willful misconduct. No provision of this Agreement or of any other Loan Document shall be deemed to impose any duty or obligation on Agent to perform any act or to exercise any power in any jurisdiction in which it shall be illegal, or shall be deemed to impose any duty or obligation on Agent to perform any act or exercise any right or power if such performance or exercise (a) would subject Agent to a Tax in a jurisdiction where it is not then subject to a Tax or (b) would require Agent to qualify to do business in any jurisdiction where it is not so qualified. Without prejudice to the generality of the foregoing, no Lender shall have any right of action whatsoever against Agent as a result of Agent acting or (where so instructed) refraining from acting under this Agreement or under any of the other Loan Documents in accordance with the instructions of Lenders. Agent shall be entitled to refrain from exercising any power, discretion or authority vested in it under this Agreement unless and until it has obtained the written instructions of Lenders. The agency hereby created shall in no way impair or affect any of the rights and powers of, or impose any duties or obligations upon Agent in its individual capacity. With respect to its participation in the Loan Agreement hereunder, Agent shall have the same rights and powers hereunder as any other Lender and may exercise the same rights and powers as though it were not performing the duties and functions delegated to it hereunder and the term "Lender" or

"Lenders" or any similar term shall unless the context clearly indicates otherwise include Agent in its individual capacity.

(c) Agent may rely, and shall be fully protected in acting, or refraining to act, upon, any resolution, statement, certificate, instrument, opinion, report, notice, request, consent, order, bond or other paper or document that it has no reason to believe to be other than genuine and to have been signed or presented by the proper party or parties or, in the case of cables, telecopies and telexes, to have been sent by the proper party or parties. In the absence of its gross negligence or willful misconduct, Agent may conclusively rely, as to the truth of the statements and the correctness of the opinions expressed therein, upon any certificates or opinions furnished to Agent and conforming to the requirements of this Agreement or any of the other Loan Documents. Agent may consult with counsel, and any opinion or legal advice of such counsel shall be full and complete authorization and protection in respect of any action taken, not taken or suffered by Agent hereunder or under any Loan Documents in accordance therewith. Agent shall have the right at any time to seek instructions concerning the administration of the Collateral from any court of competent jurisdiction. Agent shall not be under any obligation to exercise any of the rights or powers granted to Agent by this Agreement and the other Loan Documents at the request or direction of Lenders unless Agent shall have been provided by Lenders with adequate security and indemnity against the costs, expenses and liabilities that may be incurred by it in compliance with such request or direction.

(d) Each Lender agrees to indemnify Agent in its capacity as such (to the extent not reimbursed by Borrower and without limiting the obligation of Borrower to do so), according to its respective Term Commitment percentages (based upon the total outstanding Term Commitments) in effect on the date on which indemnification is sought under this Addendum 4, from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, costs, expenses or disbursements of any kind whatsoever that may at any time be imposed on, incurred by or asserted against Agent in any way relating to or arising out of, this Agreement, any of the other Loan Documents or any documents contemplated by or referred to herein or therein or the transactions contemplated hereby or thereby or any action taken or omitted by Agent under or in connection with any of the foregoing; The agreements in this Section shall survive the payment of the Loans and all other amounts payable hereunder.

(e) To the extent not reimbursed either by Borrower or from the application of Collateral proceeds pursuant to Section 10.2, a Lender (the "Indemnified Lender") shall be indemnified by the other Lenders (an "Indemnifying Lender"), on a several basis in proportion to each Lender's pro rata portion of the Term Commitment, and each Indemnifying Lender agrees to reimburse the Indemnified Lender for the Indemnifying Lender's pro rata share of the following items (an "Indemnified Payment"):

(i) all reasonable out-of-pocket costs and expenses of the Indemnified Lender incurred by the Indemnified Lender in connection with the discharge of its activities under this Agreement or the Loan Agreement, including reasonable legal expenses and attorneys' fees; provided, that the Indemnified Lender shall consult with the other Lender regarding the incurrence of such costs and expenses at reasonable intervals (but not more often than monthly) and any such reasonable costs and expenses shall be "Claims" hereunder notwithstanding any disagreement by the other Lender as to their incurrence; and

from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, costs, expenses or disbursements of any kind or nature whatsoever, which may be imposed on, incurred by or asserted against the Indemnified Lender in any way

relating to or arising out of this Agreement, or any action taken or omitted by the Indemnified Lender hereunder; provided, however, that the Indemnified Lender shall not be reimbursed or indemnified for an Indemnified Payment, except to the extent that the Indemnified Lender paid more than its ratable share of such payment. All Indemnified Payments as set forth in this clause (e) to an Indemnified Lender are intended to be paid ratably by the other Lender.

(f) [Reserved.]

(g) [Reserved.].

(h) Agent in Its Individual Capacity. The Person serving as Agent hereunder shall have the same rights and powers in its capacity as a Lender as any other Lender and may exercise the same as though it were not Agent and the term "Lender" shall, unless otherwise expressly indicated or unless the context otherwise requires, include each such Person serving as Agent hereunder in its individual capacity.

(i) Exculpatory Provisions. Agent shall have no duties or obligations except those expressly set forth herein and in the other Loan Documents. Without limiting the generality of the foregoing, Agent shall not:

(i) be subject to any fiduciary, advisory or other implied duties, regardless of whether any Default or any Event of Default has occurred and is continuing;

(ii) have any duty to take any discretionary action or exercise any discretionary powers, except discretionary rights and powers expressly contemplated hereby or by the other Loan Documents that Agent is required to exercise as directed in writing by Lenders, provided that Agent shall not be required to take any action that, in its opinion or the opinion of its counsel, may expose Agent to liability or that is contrary to any Loan Document or applicable law; and

(iii) except as expressly set forth herein and in the other Loan Documents, have any duty to disclose, and Agent shall not be liable for the failure to disclose, any information relating to Borrower or any of its Affiliates that is communicated to or obtained by any Person serving as Agent or any of its Affiliates in any capacity.

(j) In connection with any exercise of Enforcement Actions hereunder, neither any Agent nor any Lender or any of its partners, or any of their respective directors, officers, employees, attorneys, accountants, or agents shall be liable as such for any action taken or omitted by it or them, except for its or their own gross negligence or willful misconduct with respect to its duties under this Agreement.

(k) Each Lender and Agent may execute any of its powers and perform any duties hereunder either directly or by or through agents or attorneys-in-fact. Each Lender and Agent shall be entitled to advice of counsel concerning all matters pertaining to such powers and duties. No Lender or Agent shall be responsible for the negligence or misconduct of any agents or attorneys-in-fact selected by it, if the selection of such agents or attorneys-in-fact was done without gross negligence or willful misconduct.

(l) Each Lender agrees that it will make its own independent investigation of the financial condition and affairs of Borrower in connection with the making of Term Loan Advances pursuant to the Loan Agreement and has made and shall continue to make its own appraisal of the

creditworthiness of Borrower. Neither Agent nor any Lender shall have any duty or responsibility either initially or on a continuing basis to make any such investigation or any such appraisal on behalf of all Lenders or to provide the other Lenders with any credit or other information with respect thereto whether coming into its possession before the date hereof or any time or times thereafter and shall further have no responsibility with respect to the accuracy of or the completeness of the information provided to Lenders by Borrower.

ADDENDUM 5 to LOAN AND SECURITY AGREEMENT

Multiple Borrower Terms

(a) Borrower's Agent. Each Borrower hereby irrevocably appoints Company as its agent, attorney-in-fact and legal representative for all purposes, including requesting disbursement of the Term Loan and receiving account statements and other notices and communications to Borrowers (or any of them) from Agent or any Lender. Agent may rely, and shall be fully protected in relying, on any request for the Term Loan Advances, disbursement instruction, report, information or any other notice or communication made or given by Company, whether in its own name or on behalf of one or more of the other Borrowers, and Agent shall not have any obligation to make any inquiry or request any confirmation from or on behalf of any other Borrower as to the binding effect on it of any such request, instruction, report, information, other notice or communication, nor shall the joint and several character of Borrowers' obligations hereunder be affected thereby.

(b) Waivers. Each Borrower hereby waives: (i) any right to require Agent to institute suit against, or to exhaust its rights and remedies against, any other Borrower or any other person, or to proceed against any property of any kind which secures all or any part of the Secured Obligations, or to exercise any right of offset or other right with respect to any reserves, credits or deposit accounts held by or maintained with Agent or any Indebtedness of Agent or any Lender to any other Borrower, or to exercise any other right or power, or pursue any other remedy Agent or any Lender may have; (ii) any defense arising by reason of any disability or other defense of any other Borrower or any guarantor or any endorser, co-maker or other person, or by reason of the cessation from any cause whatsoever of any liability of any other Borrower or any guarantor or any endorser, co-maker or other person, with respect to all or any part of the Secured Obligations, or by reason of any act or omission of Agent or others which directly or indirectly results in the discharge or release of any other Borrower or any guarantor or any other person or any Secured Obligations or any security therefor, whether by operation of law or otherwise; (iii) any defense arising by reason of any failure of Agent to obtain, perfect, maintain or keep in force any Lien on, any property of any Borrower or any other person; (iv) any defense based upon or arising out of any bankruptcy, insolvency, reorganization, arrangement, readjustment of debt, liquidation or dissolution proceeding commenced by or against any other Borrower or any guarantor or any endorser, co-maker or other person, including without limitation any discharge of, or bar against collecting, any of the Secured Obligations (including without limitation any interest thereon), in or as a result of any such proceeding. Until Payment in Full, nothing shall discharge or satisfy the liability of any Borrower hereunder except Payment in Full. If any claim is ever made upon Agent for repayment or recovery of any amount or amounts received by Agent in payment of or on account of any of the Secured Obligations, because of any claim that any such payment constituted a preferential transfer or fraudulent conveyance, or for any other reason whatsoever, and Agent repays all or part of said amount by reason of any judgment, decree or order of any court or administrative body having jurisdiction over Agent or any of its property, or by reason of any settlement or compromise of any such claim effected by Agent with any such claimant (including without limitation the any other Borrower), then and in any such event, each Borrower agrees that any such judgment, decree, order, settlement and compromise shall be binding upon such Borrower, notwithstanding any revocation or release of this Agreement or the cancellation of any note or other instrument evidencing any of the Secured Obligations, or any release of any of the Secured Obligations, and each Borrower shall be and remain liable to Agent and Lenders under this Agreement for the amount so repaid or recovered, to the same extent as if such amount had never

originally been received by Agent or any Lender, and the provisions of this sentence shall survive, and continue in effect, notwithstanding any revocation or release of this Agreement. Each Borrower hereby expressly and unconditionally waives all rights of subrogation, reimbursement and indemnity of every kind against any other Borrower, and all rights of recourse to any assets or property of any other Borrower, and all rights to any collateral or security held for the payment and performance of any Secured Obligations, including (but not limited to) any of the foregoing rights which Borrower may have under any present or future document or agreement with any other Borrower or other person, and including (but not limited to) any of the foregoing rights which any Borrower may have under any equitable doctrine of subrogation, implied contract, or unjust enrichment, or any other equitable or legal doctrine.

(c) Consents. Each Borrower hereby consents and agrees that, without notice (except any notices expressly required by the Loan Documents) to or by Borrower and without affecting or impairing in any way the obligations or liability of Borrower hereunder, Agent may, from time to time before or after revocation of this Agreement, do any one or more of the following in its sole and absolute discretion: (i) accept partial payments of, compromise or settle, renew, extend the time for the payment, discharge, or performance of, refuse to enforce, and release all or any parties to, any or all of the Secured Obligations; (ii) grant any other indulgence to any Borrower or any other Person in respect of any or all of the Secured Obligations or any other matter; (iii) accept, release, waive, surrender, enforce, exchange, modify, impair, or extend the time for the performance, discharge, or payment of, any and all property of any kind securing any or all of the Secured Obligations or any guaranty of any or all of the Secured Obligations, or on which Agent at any time may have a Lien, or refuse to enforce its rights or make any compromise or settlement or agreement therefor in respect of any or all of such property; (iv) substitute or add, or take any action or omit to take any action which results in the release of, any one or more other Borrowers or any endorsers or guarantors of all or any part of the Secured Obligations, including, without limitation one or more parties to this Agreement, regardless of any destruction or impairment of any right of contribution or other right of Borrower; (v) apply any sums received from any other Borrower, any guarantor, endorser, or co-signer, or from the disposition of any Collateral or security, to any Indebtedness whatsoever owing from such person or secured by such Collateral or security, in such manner and order as Agent determines in its sole discretion, and regardless of whether such Indebtedness is part of the Secured Obligations, is secured, or is due and payable. Each Borrower consents and agrees that Agent shall be under no obligation to marshal any assets in favor of Borrower, or against or in payment of any or all of the Secured Obligations. Each Borrower further consents and agrees that Agent shall have no duties or responsibilities whatsoever with respect to any property securing any or all of the Secured Obligations. Without limiting the generality of the foregoing, Agent shall have no obligation to monitor, verify, audit, examine, or obtain or maintain any insurance with respect to, any property securing any or all of the Secured Obligations.

(d) Independent Liability. Each Borrower hereby agrees that one or more successive or concurrent actions may be brought hereon against such Borrower, in the same action in which any other Borrower may be sued or in separate actions, as often as deemed advisable by Agent. Each Borrower is fully aware of the financial condition of each other Borrower and is executing and delivering this Agreement based solely upon its own independent investigation of all matters pertinent hereto, and such Borrower is not relying in any manner upon any representation or statement of Agent or any Lender with respect thereto. Each Borrower represents and warrants that it is in a position to obtain, and each Borrower hereby assumes full responsibility for obtaining, any additional information concerning any other Borrower's financial condition and any other matter pertinent hereto as such Borrower may desire, and such Borrower is not relying upon or expecting

Agent to furnish to it any information now or hereafter in Agent's possession concerning the same or any other matter.

(e) Subordination. All Indebtedness of a Borrower now or hereafter arising held by another Borrower is subordinated to the Secured Obligations and Borrower holding the Indebtedness shall take all actions reasonably requested by Agent to effect, to enforce and to give notice of such subordination.

EXHIBIT K

CERTAIN ECONOMIC TERMS

"Amortization Date"	If neither the First Interest Only Extension Conditions nor the Second Interest Only Extension Conditions are satisfied: July 1, 2028. If the First Interest Only Extension Conditions are satisfied: July 1, 2029. If the Second Interest Only Extension Conditions are satisfied: the Term Loan Maturity Date.
"Approval Milestone I" Satisfaction of each of the following events:	(a) no Event of Default shall have occurred and be continuing; and (b) Borrower shall have delivered evidence satisfactory to Agent (including supporting documents as reasonably requested by Agent) that [**].
"Approval Milestone II" Satisfaction of each of the following events:	(a) no Event of Default shall have occurred and be continuing; and (b) Borrower shall have delivered evidence satisfactory to Agent (including supporting documents as reasonably requested by Agent) that [**].
"**At-the-Market Offering**"	Means sales by Borrower of shares of its capital stock that are (i) offered on a delayed or continuous basis under Rule 415 promulgated under the Act pursuant to an effective registration statement on Form S-3 under the Act, and (ii) sold from time to time at prevailing market prices through a designated broker-dealer pursuant to a written agreement between Borrower and such broker-dealer
"Commercial Milestone" Satisfaction of each of the following events:	(a) no Event of Default shall have occurred and be continuing; and (b) Borrower shall have delivered evidence satisfactory to Agent (including supporting documents as reasonably requested by Agent) that Borrower has generated Net Product Revenue, measured on a trailing three (3) month basis, of at least [**] Dollars ($[**]) for any measuring period ending by or before March 31, 2028.
"Data Milestone I" Satisfaction of each of the following events:	(a) no Event of Default shall have occurred and be continuing; and (b) Borrower shall have delivered evidence satisfactory to Agent (including supporting documents as reasonably requested by Agent) that Borrower has [**].
"Data Milestone II" Satisfaction of each of the following events:	(a) no Event of Default shall have occurred and be continuing; and (b) Borrower shall have delivered evidence satisfactory to Agent (including supporting documents as reasonably requested by Agent) that Borrower [**].
"Due Diligence Fee"	[**] Dollars ($[**])
"End of Term Charge"	(x) Five and one-half percent (5.50%) ("End of Term Charge Percentage"), *multiplied* by the aggregate original

	principal amount of such Term Loan Advances made hereunder *Minus* (y) the aggregate amount of payments made pursuant to Section 2.6(a)
"Financing Milestone" Satisfaction of each of the following events:	(a) no Event of Default shall have occurred and be continuing; and (b) Borrower shall have delivered evidence satisfactory to Agent (including supporting documents as reasonably requested by Agent) that Borrower has raised an aggregate amount of at least Three Hundred Fifty Million Dollars ($350,000,000) in Qualified Equity Issuance Net Proceeds between June 4, 2025 and December 15, 2026.
"First Interest Only Extension Conditions" Satisfaction of each of the following events:	(a) no Default or Event of Default shall have occurred and be continuing; and (b) Agent's receipt of evidence prior to July 1, 2028, in form and substance reasonably satisfactory to Agent, that the Tranche 2 Milestone has been achieved.
"Initial Facility Charge"	One Million Dollars ($1,000,000).
"Initial Minimum Cash Test Date"	April 1, 2026; provided, that the Initial Minimum Cash Test Date shall be extended to January 1, 2027 if Borrower shall have delivered evidence satisfactory to Agent (including supporting documents as reasonably requested by Agent) that Borrower has raised an aggregate amount of at least Three Hundred Fifty Million Dollars ($350,000,000) in Qualified Equity Issuance Net Proceeds between June 4, 2025 and December 15, 2026.
"Initial Minimum Revenue Test Date"	The date on or after the Initial Revenue Trigger Date on which the amount of the advanced Term Loan Advances is first greater than One Hundred Million Dollars ($100,000,000).
"Initial Revenue Trigger Date"	The date that reporting is due pursuant to Section 7.1(a) or (b) for the first calendar month or quarter, as applicable, which is nine (9) months after the earliest date that Borrower achieves either the Approval Milestone I or the Approval Milestone II.
"Maximum Term Loan Amount"	Two Hundred Seventy-Five Million Dollars ($275,000,000).
"Minimum Advance Amount"	[**] Dollars ($[**]).
"Prepayment Charge"	(a) The outstanding principal amount of each Advance amount being prepaid, *multiplied by* (b) (i) two percent (2.00%), if the principal amount of such Advance amounts are prepaid on or prior to the date which is twelve (12) months following the Closing Date;

	(ii) one and one-half percent (1.50%), if the principal amount of such Advance amounts are prepaid after the date which is twelve (12) months following the Closing Date but on or prior to the date which is twenty-four (24) months following the Closing Date; and (iii) three-quarters of one percent (0.75%), if after the date which is twenty-four (24) months following the Closing Date through the day before the Term Loan Maturity Date.
"Prime Rate"	The greater of (a) the "prime rate" as reported in *The Wall Street Journal* or any successor publication thereto and (b) seven and one-half percent (7.50%).
"Second Interest Only Extension Conditions" Satisfaction of each of the following events:	(a) no Default or Event of Default shall have occurred and be continuing; (b) the First Interest Only Extension Conditions shall have been achieved; and (c) Agent's receipt of evidence prior to July 1, 2029, in form and substance reasonably satisfactory to Agent, that the Tranche 3 Milestone has been achieved.
"Subsequent Financing"	The closing of any broadly marketed equity offering of Borrower (other than sales effected pursuant to any At-the-Market Offering) which becomes effective after the Closing Date and that Borrower reasonably expects to result in aggregate gross proceeds to Borrower of at least Fifty Million Dollars ($50,000,000).
"Subsequent Tranche Facility Charge"	[**] percent ([**]%) of any Advance (other than a Tranche 1 Advance).
"Term Commitment"	The obligation, if any, of any Lender to make a Term Loan Advance to Borrower in a principal amount not to exceed the amount set forth under the heading "Tranche 1 Commitment", "Tranche 2 Commitment", "Tranche 3 Commitment", "Tranche 4 Commitment" or "Tranche 5 Commitment", as the case may be, opposite such Lender's name on Schedule 1.1.
"Term Loan Interest Rate"	A per annum rate of interest equal to the Prime Rate *plus* two and forty-five hundredths percent (2.45%)
"Term Loan Maturity Date"	July 1, 2030.
"Tranche 1 Commitment"	The obligation, if any, of any Lender to make a Term Loan Advance to Borrower in a principal amount not to exceed the amount set forth under the heading Tranche 1 Commitment opposite such Lender's name on Schedule 1.1.
"Tranche 2 Commitment"	The obligation, if any, of any Lender to make a Term Loan Advance to Borrower in a principal amount not to exceed the amount set forth under the heading Tranche 2 Commitment opposite such Lender's name on Schedule 1.1.
~~**"Tranche 2 Commitment Period"**~~	~~The period beginning on the first date on which Borrower shall have achieved the Tranche 2 Milestone and continuing through the earlier to occur of (a) [**] and (b) the date that~~

	~~is ninety (90) days after the first date on which Borrower shall have achieved the Tranche 2 Milestone.~~
"Tranche 2 Milestone"	Borrower's achievement of at least two (2) of the following: (i) the Data Milestone I, (ii) the Data Milestone II, (iii) the Approval Milestone I, and (iv) the Financing Milestone.
"Tranche 3 Commitment"	The obligation, if any, of any Lender, if any, to make a Term Loan Advance to Borrower in a principal amount not to exceed the amount set forth under the heading Tranche 3 Commitment opposite such Lender's name on Schedule 1.1.
"Tranche 3 Commitment Period"	The period beginning on the first date on which Borrower (i) achieves the Tranche 3 Milestone and (ii) ~~either~~ draws the entire amount of the Tranche 2 Commitment ~~or the Tranche 2 Commitment Period expires~~, and continuing through the earlier to occur of (a) [**], and (b) the date that is ninety (90) days after the first date on which Borrower shall have achieved the Tranche 3 Milestone.
"Tranche 3 Milestone"	Borrower's achievement of (a) the Financing Milestone, and (b) at least two (2) of the following: (i) the Data Milestone II, (ii) the Approval Milestone I, and (iii) the Approval Milestone II.
"Tranche 4 Commitment"	The obligation, if any, of any Lender to make a Term Loan Advance to Borrower in a principal amount not to exceed the amount set forth under the heading Tranche 4 Commitment opposite such Lender's name on Schedule 1.1.
"Tranche 4 Commitment Period"	The period beginning on the first date on which Borrower (i) achieves the Tranche 4 Milestone and (ii) either draws the entire amount of the Tranche 3 Commitment or the Tranche 3 Commitment Period expires, and continuing through the earlier to occur of (a) [**], and (b) the date that is ninety (90) days after the first date on which Borrower shall have achieved the Tranche 4 Milestone.
"Tranche 4 Milestone"	Borrower's achievement of the Tranche 3 Milestone and the Commercial Milestone.
"Tranche 5 Commitment"	The obligation, if any, of any Lender to make a Term Loan Advance to Borrower in a principal amount not to exceed the amount set forth under the heading Tranche 5 Commitment opposite such Lender's name on Schedule 1.1.
"Tranche 5 Commitment Period"	The period beginning on the Closing Date and continuing until the Amortization Date.

SCHEDULE 1.1

COMMITMENTS

LENDERS	TRANCHE 1 COMMITMENT	TRANCHE 2 COMMITMENT	TRANCHE 3 COMMITMENT	TRANCHE 4 COMMITMENT	TRANCHE 5 COMMITMENT*
Hercules Capital, Inc.	[**]	[**]	[**]	[**]	[**]
Hercules Private Credit Fund 1 L.P.	[**]	[**]	[**]	[**]	[**]
Hercules Private Global Venture Growth Fund I L.P.	[**]	[**]	[**]	[**]	[**]
Hercules Venture Growth Credit Opportunities Fund I L.P.	[**]	[**]	[**]	[**]	[**]
Hercules Capital IV, L.P.	[**]	[**]	[**]	[**]	[**]
Hercules SBIC V, L.P.	[**]	[**]	[**]	[**]	[**]
TOTAL COMMITMENTS	$100,000,000	[**]	[**]	[**]	$~~60,000,000~~50,000,000*

[**]

EXHIBIT B

LOAN AND SECURITY AGREEMENT

THIS LOAN AND SECURITY AGREEMENT is made and dated as of June 27, 2025 and is entered into by and among DYNE THERAPEUTICS, INC., a Delaware corporation ("Company"), each other Person that has delivered a Joinder Agreement pursuant to Section 7.13 from time to time party hereto (together with Company, individually or collectively, as the context may require, "Borrower"), the several banks and other financial institutions or entities from time to time party hereto (each, a "Lender", and collectively "Lenders") and HERCULES CAPITAL, INC., a Maryland corporation, in its capacity as administrative agent and collateral agent for itself and Lenders (in such capacity, including any successors or assigns, "Agent").

RECITALS

A. Borrower has requested Lenders make available to Borrower up to five (5) tranches of term loans in an aggregate principal amount of up to Two Hundred Seventy-Five Million Dollars ($275,000,000) (the "Term Loans"); and

B. Lenders are willing to make the Term Loans on the terms and conditions set forth in this Agreement.

AGREEMENT

NOW, THEREFORE, Borrower, Agent and Lenders agree as follows:

SECTION 1. DEFINITIONS AND RULES OF CONSTRUCTION

1.1 Unless otherwise defined herein, the following capitalized terms shall have the following meanings:

"Account Control Agreement(s)" means any agreement entered into by and among Agent, Borrower and a third-party bank or other institution (including a Securities Intermediary) in which Borrower maintains a Deposit Account or an account holding Investment Property and which perfects Agent's first priority security interest in the subject account or accounts.

"ACH Authorization" means the ACH Debit Authorization Agreement in substantially the form of Exhibit H, which account numbers shall be redacted for security purposes if and when filed publicly by Borrower.

"Acquired Indebtedness" means, with respect to any specified Person, Indebtedness (other than indebtedness for borrowed money) of any other Person existing at the time such other Person is merged, consolidated or amalgamated with or into or became a Subsidiary of such specified Person and not incurred in connection with, or in contemplation of, such other Person merging, amalgamating or consolidating with or into, or becoming a Subsidiary of, such specified Person.

"Acquisition" means any transaction or series of related transactions for the purpose of or resulting, directly or indirectly, in (a) the acquisition of all or substantially all of the assets of a Person, or of any business, line of business or division or other unit of operation of a Person, (b) the acquisition of fifty percent (50%) or more of the Equity Interests of any Person, whether or not involving a merger, consolidation or similar transaction with such other Person, or otherwise causing any Person to become a

Subsidiary of Borrower, or (c) the acquisition of, or the right to use, develop or sell (in each case, including through licensing (other than "off-the-shelf" licenses or non-exclusive licenses that are granted in connection with services, vendor or similar contracts where the grant of intellectual property rights is ancillary to the services to be rendered or products to be provided under such contract), any product, product line or intellectual property of or from any other Person.

"Acquisition Deferred Payments" means, with respect to an Acquisition, any "earnouts," holdbacks, performance based-milestones, royalties, purchase price adjustments, profit sharing arrangements, deferred purchase money amounts, indemnifications, non-competition agreements, incentive payments, and other similar payment obligations, and other contingent obligations and agreements consisting of the adjustment of purchase price or similar adjustments.

"Advance(s)" means a Term Loan Advance.

"Advance Date" means the funding date of any Advance.

"Advance Request" means a request for an Advance submitted by Borrower to Agent in substantially the form of Exhibit A, which account numbers shall be redacted for security purposes if and when filed publicly by Borrower.

"Affiliate" means (a) any Person that directly or indirectly controls, is controlled by, or is under common control with the Person in question, (b) any Person directly or indirectly owning, controlling or holding with power to vote ten percent (10%) or more of the outstanding voting securities of another Person, (c) any Person ten percent (10%) or more of whose outstanding voting securities are directly or indirectly owned, controlled or held by another Person with power to vote such securities, or (d) any Person related by blood or marriage to any Person described in subsection (a), (b) or (c) of this definition. As used in the definition of "Affiliate," the term "control" means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through ownership of voting securities, by contract or otherwise.

"Agreement" means this Loan and Security Agreement, as amended, restated, amended and restated, supplemented or otherwise modified from time to time.

"Anti-Corruption Laws" means all laws, rules, and regulations of any jurisdiction applicable to Borrower or any of its Affiliates from time to time concerning or relating to bribery or corruption, including without limitation the United States Foreign Corrupt Practices Act of 1977, as amended, the UK Bribery Act 2010 and other similar legislation in any other jurisdictions.

"Anti-Terrorism Laws" means any laws, rules, regulations or orders relating to terrorism or money laundering, including without limitation Executive Order No. 13224 (effective September 24, 2001), the USA PATRIOT Act, the laws comprising or implementing the Bank Secrecy Act, and the laws administered by OFAC.

"Bankruptcy Code" means the federal bankruptcy law of the United States as from time to time in effect, currently as Title 11 of the United States Code. Section references to current sections of the Bankruptcy Code shall refer to comparable sections of any revised version thereof if section numbering is changed.

"Biologics License Application" means an application for licensure of a biological product submitted to the FDA under 42 U.S.C. § 262(k) for permission to introduce, or deliver for introduction, a biologic product into interstate commerce.

"Blocked Person" means any Person: (a) listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (b) owned or controlled by, or acting for or on behalf of, any Person that is listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (c) with which any Lender is prohibited from dealing or otherwise engaging in any transaction by any Anti-Terrorism Law, (d) that commits, threatens or conspires to commit or supports "terrorism" as defined in Executive Order No. 13224, or (e) that is named a "specially designated national" or "blocked person" on the most current list published by OFAC or other similar list.

"Board Approved Forecast" means the Net Product Revenue projections approved by Company's Board of Directors and delivered in accordance with Section 7.1(i), which projections must be acceptable to Agent in its reasonable discretion.

"Board of Directors" means, with respect to any Person that is a corporation, its board of directors, with respect to any Person that is a limited liability company, its board of managers, board of members or similar governing body, and with respect to any other Person that is another form of a legal entity, such Person's governing body in accordance with its Organizational Documents.

"Borrower Products" means all products, software, service offerings, technical data or technology currently being designed, manufactured or sold or that are under clinical investigation or development by Borrower or any of its Subsidiaries or which Borrower or any of its Subsidiaries intends to sell, license, or distribute in the future including any products or service offerings under development, collectively, together with all products, software, service offerings, technical data or technology that have been sold, licensed or distributed by Borrower since its incorporation and remain material to its business.

"Borrower's Books" means Borrower's or any of its Subsidiaries' books and records including ledgers, federal, state, local and foreign tax returns, records regarding Borrower's or its Subsidiaries' assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

"Business Day" means any day other than Saturday, Sunday and any other day on which banking institutions in the State of California are closed for business.

"Cash" means all cash, cash equivalents and liquid funds, in each case, excluding any Digital Assets.

"Change in Control" means (a) at any time, any "person" or "group" (as such terms are used in Sections 13(d) and 14(d) of Securities Exchange Act of 1934, as amended), shall become, or obtain rights (whether by means of warrants, options or otherwise) to become, the "beneficial owner" (as defined in Rules 13(d)-3 and 13(d)-5 under Securities Exchange Act of 1934, as amended), directly or indirectly, of more than fifty percent (50.0%) of the ordinary voting power for the election of directors, partners, managers and members, as applicable, of Company (determined on a fully diluted basis); (b) "change of control", "fundamental change", "make-whole fundamental change" or any comparable term under and as defined in any indenture governing any Permitted Convertible Debt Financing has occurred; (c) [reserved]; or (d) at any time, Company shall cease to own and control, of record and beneficially, directly or indirectly, one hundred percent (100.0%) of each class of outstanding stock, partnership, membership, or other ownership interest or other equity securities of each Subsidiary of Company, except in connection with a joint venture or strategic alliance permitted by Section 7.6 or a transaction permitted by Section 7.9, free and clear of all Liens (other than Permitted Liens).

"Charter" means, with respect to any Person, such Person's incorporation, formation or equivalent documents, as in effect from time to time.

"Closing Date" means the date of this Agreement.

"Code" means the U.S. Internal Revenue Code of 1986, as amended.

"Collateral Claim" means any and all present and future "claims" (used in its broadest sense, as contemplated by and defined in Section 101(5) of the Bankruptcy Code, but without regard to whether such claim would be disallowed under the Bankruptcy Code) of a Lender now or hereafter arising or existing under or relating to this Agreement and related Loan Documents, whether joint, several, or joint and several, whether fixed or indeterminate, due or not yet due, contingent or non-contingent, matured or unmatured, liquidated or unliquidated, or disputed or undisputed, whether under a guaranty or a letter of credit, and whether arising under contract, in tort, by law, or otherwise, any interest or fees thereon (including interest or fees that accrue after the filing of a petition by or against Borrower under the Bankruptcy Code, irrespective of whether allowable under the Bankruptcy Code), any costs of Enforcement Actions, including reasonable attorneys' fees and costs, and any prepayment or termination premiums.

"Common Stock" means the Common Stock, $0.0001 par value per share, of Company.

"Company IP" means any and all of the following, as they exist in and throughout the United States of America: (a) Current Company IP; (b) improvements, continuations, continuations-in-part, divisions, provisionals or any substitute applications, any Patent issued with respect to any of the Current Company IP, any Patent right claiming the composition of matter of, or the method of making or using, the Borrower Products in the United States of America, any reissue, reexamination, renewal or Patent term extension or adjustment (including any supplementary protection certificate) of any such Patent, and any confirmation Patent or registration Patent or patent of addition based on any such Patent; (c) trade secrets or trade secret rights, including any rights to unpatented inventions, know-how, show-how, operating manuals, confidential or proprietary information, research in progress, algorithms, data, databases, data collections, designs, processes, procedures, methods, protocols, materials, formulae, drawings, schematics, blueprints, flow charts, models, strategies, prototypes, techniques, and the results of experimentation and testing, including samples, in each case, as specifically related to any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of the Borrower Products; (d) any and all IP Ancillary Rights specifically relating to any of the foregoing; and (e) regulatory filings, submissions and approvals related to any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of the Products and all data provided in any of the foregoing.

"Compliance Certificate" means a certificate in the form attached hereto as Exhibit E.

"Contingent Obligation" means, as applied to any Person, any direct or indirect liability, contingent or otherwise, of that Person with respect to (i) any Indebtedness of another Person, including any such obligation directly or indirectly guaranteed, endorsed, co-made or discounted or sold with recourse by that Person, or in respect of which that Person is otherwise directly or indirectly liable; (ii) any obligations with respect to undrawn letters of credit, corporate credit cards or merchant services issued for the account of that Person; and (iii) all obligations arising under any interest rate, currency or commodity swap agreement, interest rate cap agreement, interest rate collar agreement, or other agreement or arrangement designed to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; provided, however, that the term "Contingent Obligation" shall not include endorsements for collection or deposit in the ordinary course of business. The amount of any Contingent Obligation shall be deemed, without duplication of the primary obligation, to be an amount equal to the stated or determined amount of the primary obligation in respect of which such Contingent Obligation is made or, if not stated or determinable, the maximum reasonably anticipated liability in respect thereof as determined by such Person in good faith; provided, however, that such amount shall not in any event exceed

the maximum amount of the obligations under the guarantee or other support arrangement. For the avoidance of doubt, no Permitted Bond Hedge Transaction or Permitted Warrant Transaction will be considered a Contingent Obligation of Borrower.

"Copyright License" means any written agreement granting any right to use any Copyright or Copyright registration, now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest.

"Copyrights" means all copyrights, whether registered or unregistered, held pursuant to the laws of the United States of America, any State thereof, or of any other country.

"Default" means any event, circumstance or condition that has occurred or exists, that would, with the passage of time or the requirement that notice be given or both, become an Event of Default.

"Deposit Accounts" means any "deposit accounts", as such term is defined in the UCC, and includes any checking account, savings account, or certificate of deposit.

"Digital Assets" means all cryptocurrencies, virtual currencies, coins, tokens and other digital assets.

"Disqualified Equity Interests" means any Equity Interests that, by their terms (or by the terms of any security or other Equity Interests into which they are convertible or for which they are exchangeable), or upon the happening of any event or condition (a) mature or are mandatorily redeemable (other than solely for Qualified Equity Interests) pursuant to a sinking fund obligation or otherwise (except as a result of a change of control or asset sale so long as any rights of the holders thereof upon the occurrence of a change of control or asset sale event shall be subject to the prior repayment in full of the Secured Obligations (other than Surviving Obligations)), (b) are redeemable at the option (except as a result of a change of control or asset sale so long as any rights of the holders thereof upon the occurrence of a change of control or asset sale event shall be subject to the prior repayment in full of the Secured Obligations (other than Surviving Obligations)) of the holder thereof (other than solely for Qualified Equity Interests), in whole or in part, (c) provide for scheduled payments of dividends in Cash, or (d) are or become convertible into or exchangeable for Indebtedness or any other Equity Interests that would constitute Disqualified Equity Interests, in each case, prior to the date that is one hundred eighty (180) days after the Term Loan Maturity Date; provided that if such Equity Interests are issued pursuant to any plan for the benefit of any employee, officer, director, manager or consultant of a Loan Party, any Subsidiary thereof, or by any such plan to such employee, officer, director, manager or consultant, such Equity Interests shall not constitute Disqualified Equity Interests solely because they may be required to be repurchased by a Loan Party or any Subsidiary thereof in order to satisfy applicable statutory or regulatory obligations or as a result of the termination, death or disability of such employee, officer director, manager or consultant.

"Division" means, in reference to any Person which is an entity, the division of such Person into two (2) or more separate Persons, with the dividing Person either continuing or terminating its existence as part of such division, including, without limitation, as contemplated under Section 18-217 of the Delaware Limited Liability Company Act for limited liability companies formed under Delaware law, Section 17-220 of the Delaware Revised Uniform Limited Partnership Act for limited partnerships formed under Delaware law, or any analogous action taken pursuant to any other applicable law with respect to any corporation, limited liability company, partnership or other entity.

"Domestic Subsidiary" means any Subsidiary organized under the laws of the United States of America, any State thereof, the District of Columbia, or any other jurisdiction within the United States of America.

"Enforcement Action" means, with respect to any Lender and with respect to any Collateral Claim of such Lender or any item of Collateral in which such Lender has or claims a security interest lien or right of offset, any action, whether judicial or nonjudicial, to repossess, collect, accelerate, offset, recoup, give notification to third parties with respect to, sell, dispose of, foreclose upon, give notice of sale, disposition, or foreclosure with respect to, or obtain equitable or injunctive relief with respect to, such Collateral Claim or Collateral. The filing, or the joining in the filing, by any Lender of an involuntary bankruptcy or Insolvency Proceeding against Borrower also is an Enforcement Action.

"Equity Interests" means, with respect to any Person, the capital stock, partnership or limited liability company interest, or other equity securities or equity ownership interests of such Person.

"ERISA" means the Employee Retirement Income Security Act of 1974, as amended, and the regulations promulgated thereunder.

"Excluded Accounts" means any of the following Deposit Accounts which are designated as such in writing to Agent as of the Closing Date or, with respect to any Deposit Account opened after the Closing Date, in the next Compliance Certificate delivered after such Deposit Account is opened: (a) Deposit Accounts exclusively used for payroll, payroll taxes, and other employee wage and benefit payments to or for the benefit of Borrower's employees holding an aggregate amount across all such accounts of not more than amounts needed for the then-next two (2) payroll cycles, (b) any Deposit Account which is a zero-balance disbursement account, (c) any Deposit Account which is solely used for disbursements and payments of withheld income taxes, payroll taxes and/or federal, state or local employee taxes, (d) any Deposit Account which is solely used as a trust account, escrow account, or other fiduciary account, and (e) accounts used exclusively to maintain cash collateral subject to a Permitted Lien.

"Excluded Subsidiaries" means (a) the MSC Subsidiary, and (b) all Foreign Subsidiaries that (i) generate in the aggregate less than 5.00% of the consolidated trailing twelve month revenue calculated in accordance with GAAP of the Company and its Subsidiaries as of the last day of the most recent fiscal month for which financial statements of the Company are available, (ii) hold in the aggregate assets that constitute less than 5.00% of consolidated total assets of the Company and its Subsidiaries, at any time, (iii) hold in the aggregate Cash less than of One Million Dollars ($1,000,000) at any time, and (iv) holds no Intellectual Property; provided that, notwithstanding the foregoing, an Excluded Subsidiary may license Intellectual Property on a non-exclusive basis or own de minimis Intellectual Property such as Trademarks protecting its name or logo; provided further that, if the aforementioned thresholds are exceeded at any time, then Borrower shall designate in writing to the Agent one or more of such Foreign Subsidiaries to become a Borrower to the extent necessary to eliminate such excess.

"FDA" means the U.S. Food and Drug Administration or any successor thereto.

"FDA Laws" means all applicable guidelines, policies and Requirements of Law administered, implemented, enforced or issued by FDA or any comparable governmental authority.

"First Amendment Closing Date" means December 8, 2025.

"Foreign Subsidiary" means a Subsidiary other than any Domestic Subsidiary.

"Funding Account" means the deposit account maintained by [**], bearing account number [**] in which Borrower has an interest (which, for the avoidance of doubt, shall be the account into which the proceeds of the Loan will be funded into on the Closing Date).

"GAAP" means generally accepted accounting principles in the United States of America, as in effect from time to time.

"Governmental Approval" means any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

"Governmental Authority" means any federal, state, municipal, national or other government, governmental department, commission, board, bureau, court, agency or instrumentality or political subdivision thereof (including the FDA) or any entity or officer exercising executive, legislative, judicial, regulatory or administrative functions of or pertaining to any government or any court, in each case whether associated with a state or locality of the United States, the United States, or a foreign government.

"Guarantor" means any Subsidiary of Borrower that enters into a Guaranty.

"Guaranty" means a guaranty with respect to the Secured Obligations, in form and substance satisfactory to Agent that may be entered into from time to time, as the same may from time to time be amended, restated, modified or otherwise supplemented.

"Hedge Agreement" means any interest rate, currency or commodity swap agreement, interest rate cap agreement, interest rate collar agreement, fuel or mineral or other commodity hedge or exchange agreement or any other agreement or arrangement entered into for non-speculative purposes designated to protect a Person against fluctuation in interest rates currency exchange rates, commodity or mineral prices other than in connection with a Permitted Bond Hedge Transaction or Permitted Warrant Transaction.

"Indebtedness" means indebtedness of any kind, including (a) all indebtedness for borrowed money or the deferred purchase price of property or services (excluding trade credit entered into in the ordinary course of business due within ninety (90) days), including reimbursement and other obligations with respect to surety bonds and letters of credit, (b) all obligations evidenced by notes, bonds, debentures or similar instruments, (c) all capital lease obligations, (d) all obligations to purchase, redeem, retire or defease Disqualified Equity Interests, (e) "earnouts", purchase price adjustments, profit sharing arrangements, deferred purchase money amounts and similar payment obligations or continuing obligations of any nature arising out of purchase and sale contracts but only in each case of the foregoing as and to the extent of the amount required to be reflected as a liability on the balance sheet of such Person in accordance with GAAP, (f) [reserved], (g) non-contingent obligations to reimburse any bank or Person in respect of amounts paid under a letter of credit, banker's acceptance or similar instrument, and (h) all Contingent Obligations. For the avoidance of doubt, no Permitted Bond Hedge Transaction or Permitted Warrant Transaction will be considered Indebtedness of Borrower.

"Insolvency Proceeding" means any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy, liquidation, moratorium, receivership, or insolvency law, including assignments for the benefit of creditors, compositions, extensions generally with its creditors, or proceedings seeking reorganization, administration, arrangement, receivership or other similar relief proceedings in the applicable jurisdiction from time to time in effect and affecting the rights of creditors generally.

"Intellectual Property" means all of Borrower's Copyrights; Trademarks; Patents; Licenses; trade secrets and inventions; mask works; Borrower's applications therefor and reissues, extensions, or renewals thereof; and Borrower's goodwill associated with any of the foregoing, together

with Borrower's rights to sue for past, present and future infringement of Intellectual Property and the goodwill associated therewith.

"Intellectual Property Security Agreement" means the Intellectual Property Security Agreement dated as of the Closing Date between Loan Parties and Agent, as the same may from time to time be amended, restated, modified or otherwise supplemented.

"Investment" means (a) any beneficial ownership (including stock, shares, partnership interests, limited liability company interests, or other equity securities or ownership interests) of or in any Person, (b) any loan, advance or capital contribution to any Person, (c) any Acquisition, or (d) other transfers on behalf of or in connection with any equity ownership or similar transfers.

"IP Ancillary Rights" means, with respect to any Copyright, Trademark, Patent, software, trade secrets or trade secret rights, including any rights to unpatented inventions, know-how, show-how and operating manuals, all income, royalties, proceeds and liabilities at any time due or payable or asserted under or with respect to any of the foregoing or otherwise with respect thereto, including all rights to sue or recover at law or in equity for any past, present or future infringement, misappropriation, dilution, violation or other impairment thereof, and, in each case, all rights to obtain any other intellectual property right ancillary to any Copyright, Trademark, Patent, software, trade secrets or trade secret rights.

"IRS" means the U.S. Internal Revenue Service.

"Joinder Agreements" means for each Subsidiary required to join as a Borrower or as a Guarantor pursuant to Section 7.13, a completed and executed Joinder Agreement in substantially the form attached hereto as Exhibit F.

"License" means any Copyright License, Patent License, Trademark License or other Intellectual Property license of rights or interests.

"Lien" means any mortgage, deed of trust, pledge, hypothecation, assignment for security, security interest, encumbrance, levy, lien or charge of any kind, whether voluntarily incurred or arising by operation of law or otherwise, against any property, any conditional sale or other title retention agreement, and any lease in the nature of a security interest.

"Loan" means the Advances made under this Agreement.

"Loan Documents" means this Agreement, the promissory notes (if any), the ACH Authorization, the Account Control Agreements, any Joinder Agreement, all UCC Financing Statements, any Guaranty, the Pledge Agreement, the Intellectual Property Security Agreement, and any other documents executed in connection with the Secured Obligations or the transactions contemplated hereby, as the same may from time to time be amended, modified, supplemented or restated.

"Loan Party" means Borrower or any Guarantor.

"Market Capitalization" means, for any given date of determination, an amount equal to (a) the average of the daily volume weighted average price of Company's common Equity Interests as reported for each of the five (5) Trading Days preceding such date of determination *multiplied by* (b) the total number of issued and outstanding shares of Company's common Equity Interests that are issued and outstanding on the date of the determination and listed on the Principal Stock Exchange, subject to appropriate adjustment for any stock dividend, stock split, stock combination, reclassification or other similar transaction during the applicable calculation period.

"Market Disruption Event" means any of the following events: (a) any suspension of, or limitation imposed on, trading by the Principal Stock Exchange in shares of common Equity Interests during any period or periods aggregating one hour or longer and whether by reason of movements in price exceeding limits permitted by the Principal Stock Exchange or otherwise relating to the common Equity Interests; or (b) the failure to open of the exchange or quotation system on which the common Equity Interests are traded or the closure of such exchange or quotation system prior to its respective scheduled closing time for the regular trading session on such day (without regard to after hours or other trading outside the regular trading session hours).

"Material Adverse Effect" means a material adverse effect upon: (i) the business, operations, properties, assets or financial condition of the Loan Parties and their respective Subsidiaries taken as a whole; or (ii) the ability of Borrower to perform or pay the Secured Obligations in accordance with the terms of the Loan Documents, or the ability of Agent or Lenders to enforce any of its rights or remedies with respect to the Secured Obligations; or (iii) the Collateral or Agent's Liens on the Collateral or the priority of such Liens.

"Material Agreement" means any license, agreement or other contractual arrangement the termination of which before the end of its stated term could be reasonably expected to result in a Material Adverse Effect individually or in the aggregate.

"Material Regulatory Liabilities" means (a) (i) any liabilities arising from the violation of applicable laws, rules or regulations (including FDA Laws), or necessary to remedy any violation of any terms or conditions applicable to any Registrations), including, but not limited to, withdrawal of approval, recall, revocation, suspension, import detention and seizure of any Borrower Product, and (ii) any loss of recurring annual revenues as a result of any loss, suspension or limitation of any Registrations, which, in the case of the foregoing clauses (i) and (ii), could reasonably be expected to result in a Material Adverse Effect.

"Milestone" means, individually and collectively, Data Milestone I, Data Milestone II, Approval Milestone 1, Approval Milestone 2, Commercial Milestone and Financing Milestone.

"MSC Investment Conditions" means that Borrower maintains Qualified Cash in an amount equal to or greater than the lesser of (i) one hundred percent (100%) of the aggregate outstanding Secured Obligations (inclusive of any Prepayment Charge and End of Term Charge that would be due and owing if the outstanding Loans were prepaid at the time of measurement) or (ii) one hundred percent (100%) of the consolidated Cash of Borrower and its Subsidiaries (other than Cash held in an Excluded Account), unless compliance with the foregoing conditions are waived in writing from time to time by Agent (in its sole discretion) with respect to specified periods.

"MSC Subsidiary" means Dyne Therapeutics Securities Corporation, a wholly-owned Subsidiary incorporated in the Commonwealth of Massachusetts for the purpose of holding Investments as a Massachusetts security corporation under 830 CMR 63.38B.1 of the Massachusetts tax code and applicable regulations (as the same may be amended, modified or replaced from time to time).

"Net Product Revenue" means Borrower's net product revenue (as determined in accordance with GAAP) solely from the sale of DYNE-101 and DYNE-251, which shall not include any royalty, profit sharing, sales-based milestone revenue, upfront or non-sales-based milestone payments under business development or licensing transactions, measured on as of the date of the most recently delivered monthly or quarterly financial statements in accordance with Section 7.1(a) or Section 7.1(b). For the avoidance of doubt, net product revenue shall not include any of the following to the extent not recognizable as revenue in accordance with GAAP: (i) trade, quantity and cash discounts allowed by

Borrower, (ii) discounts, refunds, rebates, charge backs, retroactive price adjustment and any other allowances which effectively reduce net selling price, (iii) product returns and allowances, (iv) allowances for shipping or other distribution expenses, (v) set-offs and counterclaims, and (vi) any other similar and customary deductions that are typically deducted from gross revenue and not included in net revenue in accordance with GAAP.

"Non-Disclosure Agreement" means that certain Confidentiality Agreement by and between Company and Agent dated as of [**].

"OFAC" means the U.S. Department of Treasury Office of Foreign Assets Control.

"OFAC Lists" means, collectively, the Specially Designated Nationals and Blocked Persons List maintained by OFAC pursuant to Executive Order No. 13224, 66 Fed. Reg. 49079 (Sept. 25, 2001) and/or any other list of terrorists or other restricted Persons maintained pursuant to any of the rules and regulations of OFAC or pursuant to any other applicable Executive Orders.

"Organizational Documents" means with respect to any Person, such Person's Charter, and (a) if such Person is a corporation, its bylaws, (b) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (c) if such Person is a partnership, its partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto.

"Paid in Full", "Pay in Full" or "Payment in Full" shall mean the indefeasible payment in full in cash of all Secured Obligations other than inchoate indemnification obligations which, by their terms, survive termination of this Agreement (such obligations, "Surviving Obligations") and Lenders have no further commitment or obligation hereunder or under any other Loan Documents to make any further Advances.

"Patent License" means any written agreement granting any right with respect to any invention on which a Patent is in existence or a Patent application is pending, in which agreement Borrower now holds or hereafter acquires any interest.

"Patents" means all letters patent of, or rights corresponding thereto, in the United States of America or in any other country, all registrations and recordings thereof, and all applications for letters patent of, or rights corresponding thereto, in the United States of America or any other country.

"Perfection Certificate" means a completed certificate entitled "Perfection Certificate", dated as of the Closing Date, delivered by Company to Agent and Lenders, signed by Company (as amended or supplemented pursuant to the terms of this Agreement).

"Permitted Acquisition" means any Acquisition which is conducted in accordance with the following requirements:

(i) of a business or Person or product engaged in a line of business related to that of Borrower or its Subsidiaries;

(ii) if such Acquisition is structured as a stock acquisition, then the Person so acquired shall (a) be domiciled in the United States of America, and (b) either (1) become a wholly-owned Subsidiary of Borrower or of a Subsidiary and Borrower shall comply, or cause such Subsidiary to comply, with Section 7.13 or (2) such Person shall be merged with and into Borrower (with Borrower being the surviving entity);

(iii) if such Acquisition is structured as the acquisition or in-licensing of assets, the assets acquired in the case of an acquisition (or, in the case of in-licensing, the rights to use such assets in accordance with the license agreement) shall be (a) except for de-minimis assets or any assets acquired in an in-licensing transaction, located entirely in the United States of America, (b) acquired by Borrower or a newly-organized wholly-owned Subsidiary (in which event such Subsidiary shall comply with Section 7.13 hereof), and (c) free and clear of Liens other than Permitted Liens;

(iv) Borrower shall have delivered to Lenders not less than fifteen (15) (or such shorter period as Agent may agree) nor more than forty five (45) days prior to the closing date of such Acquisition, (a) notice of such Acquisition together with copies of all material documents relating to such Acquisition, and, (b) in the case of a stock acquisition or the acquisition of a division or line of business, pro forma projected financial information and historical financial statements for such acquired entity, division or line of business (in each case, to the extent applicable), in each case in a form reasonably satisfactory to Lenders and demonstrating compliance with the covenants set forth in Section 7.21 then in effect on a pro forma basis as if the Acquisition occurred on the first day of the most recent measurement period;

(v) both immediately before and after such Acquisition no Default or Event of Default shall have occurred and be continuing; and

(vi) the sum of the purchase price of such proposed new Acquisition, computed on the basis of total acquisition consideration paid or incurred, or to be paid or incurred, by Borrower with respect thereto, including any unpaid Acquisition Deferred Payment that is not required to be reflected as a liability on the balance sheet of Borrower in accordance with GAAP, and including the amount of Permitted Indebtedness assumed or to which such assets, businesses or business or ownership interest or shares, or any Person so acquired, is subject, shall not be greater than (x) until such time as Borrower achieves either Approval Milestone I or the Approval Milestone II (i) [**] Dollars ($[**]) per fiscal year for any single acquisition or group of related acquisitions or (ii) [**] Dollars ($[**]) for all such acquisitions during the term of this Agreement and (y) after Borrower achieves either Approval Milestone I or the Approval Milestone II (i) [**] Dollars ($[**]) per fiscal year for any single acquisition or group of related acquisitions or (ii) [**] Dollars ($[**]) for all such acquisitions during the term of this Agreement; provided that (1) acquisition consideration funded by proceeds from the sale and issuance of Borrower's Qualified Equity Interests in a transaction not resulting in a Change in Control, which sale and issuance has a primary purpose to fund such Acquisition, and which sale and issuance is consummated substantially contemporaneously with (and in any event, prior to, but no more than thirty (30) days prior to) the consummation of such Acquisition, shall be disregarded in determining compliance with this clause (vi); (2) for any Acquisition in which the consideration consists solely of Qualified Equity Interests of Borrower, the value of such Qualified Equity Interests shall be disregarded in determining compliance with this clause (vi).

"Permitted Bond Hedge Transaction" means any call or capped call option (or substantively equivalent derivative transaction) relating to Common Stock (or other securities or property following a merger event or other change of Common Stock) purchased by Borrower in connection with the issuance of any Permitted Convertible Debt Financing.

"Permitted Convertible Debt Financing" means issuance by Company of convertible notes in one or more transactions in an aggregate principal amount of not more than [**] Dollars ($[**]) ("Permitted Convertible Debt"); provided that such convertible notes shall (a) both immediately prior to and immediately after giving effect (including pro forma effect) thereto, no Default or Event of Default

shall exist or result therefrom, (b) have no scheduled amortization or principal payments, mandatory redemptions or other required payments of principal prior to the date that is one hundred eighty (180) days after the Term Loan Maturity Date, other than customary payments upon a "change of control", "fundamental change", "make-whole fundamental change" or any comparable term (it being understood that a holder's option to convert any such Indebtedness into Common Stock (and Cash in lieu of fractional shares) shall not be considered a required mandatory redemption or payment of principal and payments of interest shall be permitted), (c) be unsecured or secured, (d) not be guaranteed by any Subsidiary of Company that is not a Borrower or a guarantor of the Secured Obligations, (e) if secured, contain usual and customary subordination terms for underwritten offerings of senior subordinated convertible notes, (f) shall be Indebtedness of Company and not of any Subsidiary thereof, and (g) if secured, shall specifically designate this Agreement and all Secured Obligations as "designated senior indebtedness" or similar term so that the subordination terms referred to in clause (e) of this definition specifically refer to such notes as being subordinated to the Secured Obligations pursuant to such subordination terms. For the avoidance of doubt, Permitted Convertible Debt Financing shall not constitute Subordinated Indebtedness.

"Permitted Indebtedness" means:

(i) Indebtedness of Borrower in favor of any Lender or Agent arising under this Agreement or any other Loan Document;

(ii) Indebtedness existing on the Closing Date which is disclosed in Schedule 1A;

(iii) Indebtedness of up to [**] Dollars ($[**]) outstanding at any time secured by a Lien described in clause (vii) of the defined term "Permitted Liens," provided such Indebtedness does not exceed the cost of the Equipment, software or other Intellectual Property financed with such Indebtedness plus customary fees, expenses and taxes;

(iv) Indebtedness to trade creditors incurred in the ordinary course of business (other than trade credit that is past due by more than one hundred twenty (120) days), including such Indebtedness incurred in the ordinary course of business with corporate credit cards in an aggregate outstanding amount not to exceed [**] Dollars ($[**]) at any time;

(v) Indebtedness that also constitutes a Permitted Investment or is secured by a Permitted Lien;

(vi) Subordinated Indebtedness;

(vii) reimbursement obligations in connection with letters of credit or Hedge Agreements (entered into in order to manage existing or anticipated interest rate, exchange rate or commodity price risks and not for speculative purposes), that are at any time outstanding and secured by Cash and issued on behalf of Borrower or a Subsidiary in an amount not to exceed [**] Dollars ($[**]);

(viii) other unsecured Indebtedness in an amount not to exceed [**] Dollars ($[**]) at any time outstanding;

(ix) intercompany Indebtedness of (A) any Loan Party owing to another Loan Party, or (B) any Foreign Subsidiary that is an Excluded Subsidiary resulting from a Permitted Investment in accordance with clause (x) of the defined term "Permitted Investments";

(x) the Permitted Convertible Debt Financing;

(xi) Indebtedness with respect to a Permitted Royalty Transaction;

(xii) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of business;

(xiii) Indebtedness consisting of financing of insurance premiums in the ordinary course of business;

(xiv) Indebtedness in respect of netting services, overdraft protection and similar arrangements in connection with deposit or securities accounts in the ordinary course of business;

(xv) Indebtedness consisting of guarantees with respect to surety and appeal bonds, performance bonds, bid bonds, appeal bonds, completion guarantees, and similar obligations up to an aggregate amount of [**] Dollars ($[**]) at any one time outstanding;

(xvi) Acquired Indebtedness not to exceed [**] Dollars ($[**]) outstanding;

(xvii) Indebtedness in respect of Acquisition Deferred Payments incurred in connection with Permitted Acquisitions;

(xviii) the Thermo Fisher Installment Payments, subject to the terms and conditions of Section 7.25 of this Agreement; and

(xix) extensions, refinancings and renewals of any items of Permitted Indebtedness, provided that the principal amount is not increased or the terms modified to impose materially more burdensome (taken as a whole) terms upon Borrower or its Subsidiary, as the case may be.

"Permitted Investment" means:

(i) Investments existing on the Closing Date which are disclosed in Schedule 1B;

(ii) (a) marketable direct obligations issued or unconditionally guaranteed by the United States of America or any agency or any State thereof maturing within one year from the date of acquisition thereof currently having a rating of at least A-2 or P-2 from either Standard & Poor's Corporation or Moody's Investors Service, (b) commercial paper maturing no more than one year from the date of creation thereof and currently having a rating of at least A-2 or P-2 from either Standard & Poor's Corporation or Moody's Investors Service, (c) certificates of deposit maturing no more than one year from the date of investment therein, which are either (x) issued by any bank with assets of at least Five Hundred Million Dollars ($500,000,000), or (y) are fully FDIC-insured, (d) money market accounts, and (e) Investments permitted by Borrower's investment policy as provided to Agent and Lenders prior to the Closing Date, as amended from time to time; provided that any material amendments thereto have been approved in writing by Agent and the Lenders in their reasonable discretion;

(iii) repurchases of stock of Borrower from former employees, directors, or consultants of Borrower under the terms of applicable repurchase agreements at the original issuance price of such securities in an aggregate amount not to exceed [**] Dollars ($[**]) in any fiscal year, provided that no Event of Default has occurred, is continuing or would exist after giving effect to the repurchases;

(iv) Investments accepted in connection with Permitted Transfers;

(v) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of Borrower's business;

(vi) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business, provided that this subsection (vi) shall not apply to Investments of any Loan Party in any Subsidiary of a Loan Party;

(vii) Investments consisting of loans not involving the net transfer on a substantially contemporaneous basis of cash proceeds to employees, officers or directors relating to the purchase of capital stock of Company pursuant to employee stock purchase plans or other similar agreements approved by Company's Board of Directors;

(viii) Investments consisting of: (A) travel advances and employee relocation loans in the ordinary course of business, and (B) loans to employees, officers, managers or directors relating to the purchase of equity securities of Borrower pursuant to employee stock purchase plans or agreements approved by Borrower's Board of Directors or similar governing body; not to exceed [**] Dollars ($[**]) in the aggregate for (A) and (B), collectively, from the Closing Date until Payment in Full;

(ix) Investments in newly-formed Subsidiaries, provided that each such Subsidiary has complied with Section 7.13;

(x) Investments in Foreign Subsidiaries that are Excluded Subsidiaries (including newly-formed Foreign Subsidiaries) not to exceed [**] Dollars ($[**]) in the aggregate in any fiscal year, and other amounts approved in advance in writing by Agent;

(xi) Investments in the MSC Subsidiary, so long as an Event of Default does not exist at the time of such Investment and would not exist after giving effect to such Investment and provided that Borrower is, before and after giving effect to such Investment, in compliance with the MSC Investment Conditions;

(xii) joint ventures or strategic alliances in the ordinary course of Borrower's business consisting of the nonexclusive licensing of technology, the development of technology or the providing of technical support, provided that any cash Investments by Borrower do not exceed [**] Dollars ($[**]) in the aggregate in any fiscal year; and provided, further, that, for the avoidance of doubt, any cost-sharing arrangements in connection with collaborative studies with third parties shall not be subject to any such limitation;

(xiii) Investments constituting Permitted Acquisitions;

(xiv) Investments consisting of Deposit Accounts and securities accounts permitted by this Agreement; and

(xv) additional Investments that do not exceed [**] Dollars ($[**]) in the aggregate.

"Permitted Liens" means:

(i) Liens in favor of Agent or Lenders;

(ii) Liens existing on the Closing Date which are disclosed in Schedule 1C;

(iii) Liens for taxes, fees, assessments or other governmental charges or levies, either not yet due or being contested in good faith by appropriate proceedings diligently conducted; provided, that Borrower maintains adequate reserves therefor on Borrower's Books in accordance with GAAP;

(iv) Liens securing claims or demands of materialmen, artisans, mechanics, carriers, warehousemen, landlords and other like Persons arising in the ordinary course of Borrower's business and imposed without action of such parties; provided, that the payment thereof is not yet required;

(v) Liens arising from judgments, decrees or attachments in circumstances which do not constitute an Event of Default hereunder;

(vi) the following deposits, to the extent made in the ordinary course of business: deposits under worker's compensation, unemployment insurance, social security and other similar laws, or to secure the performance of bids, tenders or contracts (other than for the repayment of borrowed money) or to secure indemnity, performance or other similar bonds for the performance of bids, tenders or contracts (other than for the repayment of borrowed money) or to secure statutory obligations (other than Liens arising under ERISA or environmental Liens) or surety or appeal bonds, or to secure indemnity, performance or other similar bonds;

(vii) Liens on Equipment or software or other intellectual property constituting purchase money Liens and other Liens in connection with capital leases securing Indebtedness permitted in clause (iii) of "Permitted Indebtedness";

(viii) Liens incurred in connection with Subordinated Indebtedness;

(ix) leasehold interests in leases or subleases and licenses (other than with respect to Intellectual Property) granted in the ordinary course of business and not interfering in any material respect with the business of the licensor;

(x) Liens in favor of customs and revenue authorities arising as a matter of law to secure payment of custom duties that are promptly paid on or before the date they become due;

(xi) Liens on insurance proceeds securing the payment of financed insurance premiums that are promptly paid on or before the date they become due (provided that such Liens extend only to such insurance proceeds and not to any other property or assets);

(xii) statutory and common law rights of set-off and other similar rights as to deposits of cash and securities in favor of banks, other depository institutions and brokerage firms;

(xiii) easements, servitudes, zoning restrictions, rights-of-way and similar encumbrances on real property imposed by law or arising in the ordinary course of business so long as they do not materially impair the value or marketability of the related property;

(xiv) (a) Liens on Cash securing obligations permitted under clause (vii) of the definition of Permitted Indebtedness and (b) security deposits in connection with real property leases, the combination of (a) and (b) in an aggregate amount not to exceed [**] Dollars ($[**]) at any time;

(xv) Licenses that qualify as Permitted Transfers;

(xvi) Liens in connection with a Permitted Royalty Transaction consisting of (i) Liens or back-up Liens solely on the royalty interest purchased pursuant to a true sale Permitted Royalty Transaction and the proceeds thereof, and segregated accounts into which such purchased royalty interests (and only such royalty interests) are paid (such account, a "Permitted Segregated Royalty Account"), or (ii) Liens on Company IP that comply with clause (b) of the definition of Permitted Royalty Transaction;

(xvii) Liens solely on any Cash earnest money deposits made by Borrower or any of its Subsidiaries in connection with any letter of intent or purchase agreement that constitutes a Permitted Acquisition in an aggregate amount not to exceed [**] percent ([**]%) of the aggregate purchase consideration paid in connection thereto; and

(xviii) Liens incurred in connection with the extension, renewal or refinancing of the Indebtedness secured by Permitted Liens; provided, that any extension, renewal or replacement Lien shall be limited to the property encumbered by the existing Lien and the principal amount of the Indebtedness being extended, renewed or refinanced (as may have been reduced by any payment thereon) does not increase.

"Permitted Out-Licenses" means licenses, sub-licenses and similar arrangements for the use of the Intellectual Property entered into on arms' length basis, that could not result in a legal transfer of title of the licensed property and which may be exclusive in respects other than territory, and with respect to territory shall be either: (a) non-exclusive; (b) exclusive but only as to discrete geographical areas outside of the United States of America; (c) exclusive as to specific geographic regions or territories including the United States but only as it relates to assets other than DYNE-101 and DYNE-251 for the Duchenne muscular dystrophy or myotonic dystrophy type 1 indications; provided, that, with respect to this clause (c), the same is for a specific disease indication and/or a specific drug target such that it does not limit the use of the Borrower's technology platform in a manner that would prevent Borrower from continuing to develop DYNE-101 and DYNE-251 in the United States or being able to further develop and transact its technology platform. Agent shall, if reasonably requested by Borrower, enter into customary non-disturbance agreements, in form and substance reasonably acceptable to Agent, in connection with the entry by Borrower or any Subsidiary into any out-license that constitutes a Permitted Out-License.

"Permitted Transfers" means:

(i) sales of Inventory in the ordinary course of business;

(ii) Permitted Out-Licenses;

(iii) transfers by and among Borrower and any Subsidiary that has executed a Joinder Agreement;

(iv) transfers constituting the making of Permitted Investments, or the granting of Permitted Liens;

(v) dispositions of worn-out, obsolete or surplus Equipment at fair market value in the ordinary course of business; and

(vi) Transfers consisting of royalty payments in connection with any Permitted Royalty Transaction;

(vii) use of Cash in the ordinary course of business to the extent not prohibited pursuant to the terms of the Loan Documents;

(viii) the sale of Qualified Equity Interests to the extent not causing a Change in Control;

(ix) the abandonment, cancellation, allowing to lapse, or other disposition of any Patents, Trademarks or Copyrights that are no longer used or useful to the Loan Parties or, subject to Agent's approval, which shall not be unreasonably withheld or delayed, are no longer economically practicable to maintain; *provided* that absence of receipt of Agent's approval by Borrower within 5 Business Days following Borrower providing notice of such decision shall be deemed to be Agent's approval; and *provided, further*, that Agent's approval shall not be required in relation to routine decisions concerning ex-US and national stage filing strategies occurring in the normal course of prosecution or for any abandonment, cancellation, allowance to lapse, or other disposition that does not result in a complete loss of rights in relation to the Patents, Trademarks, or Copyrights (such as abandoning a patent application in favor of a continuation or divisional application);

(x) subleases of real property or the termination of real property leases in the ordinary course of business;

(xi) transactions permitted under Section 7.9; and

(xii) other Transfers of assets having a fair market value of not more than [**] Dollars ($[**]) in the aggregate in any fiscal year.

"Permitted Royalty Transaction" means either a true royalty or synthetic royalty financing whereby Borrower receives or has rights to receive unencumbered and unrestricted (including, not subject to any redemption, clawback, escrow or similar encumbrance or restriction, but excluding encumbrances and restrictions under the Loan Documents) net cash proceeds of no less than [**] Dollars ($[**]) (or, if a lesser percentage of revenue is sold, no less than a pro-rated amount based on such lesser percentage) in exchange for rights to receive future payments based on net sales, revenue or milestones, as applicable, of DYNE-101 and/or DYNE-251 in an amount not to exceed, in the aggregate for all such Permitted Royalty Transactions, [**] percent ([**]%) (or, if a lesser amount of cash proceeds is to be received, no less than a pro-rated percentage based on such lesser amount) of worldwide net sales or revenue, as applicable, of DYNE-101 and/or DYNE-251; provided that such transaction (a) in the case of any synthetic royalty financings (and not royalty purchases or buyouts) with respect to DYNE-101 and/or DYNE-251, shall be subject to an intercreditor agreement in form and substance satisfactory to Agent in its sole discretion, (b) for which any security is granted, shall have such grant of security limited solely to DYNE-101 and/or DYNE-251 and such security is subordinated to Agent's first priority Lien, and (c) shall not have a guaranteed minimum return payment or "true-up" payment earlier than one hundred eighty (180) days after the Term Loan Maturity Date and/or subject to Payment in Full and if structured as Indebtedness, shall not have a scheduled maturity date earlier than one hundred eighty (180) days after the Term Loan Maturity Date; provided further that Borrower shall not engage in more than one such transaction, for each of DYNE-101 and DYNE-251, at any one time. For the avoidance of doubt, the aforementioned figures shall be

scalable (e.g. an amount not less than [**] Dollars ($[**]) for each transaction in exchange for a promise to pay future royalties on net sales of not more than [**]% of total DYNE-101 and/or [**]% of total DYNE-251 net product revenue). Agent shall, if requested by Borrower, release its Lien on purchased revenue streams in connection with a "true sale" of an existing revenue stream that (i) constitutes a Permitted Royalty Transaction, and (ii) is not a synthetic royalty transaction as determined by the Agent in its reasonable business judgment.

"Permitted Warrant Transaction" means any call option, warrant or right to purchase (or substantively equivalent derivative transaction) relating to Common Stock (or other securities or property following a merger event or other change of the Common Stock) and/or cash (in an amount determined by reference to the price of such Common Stock) sold by Borrower in connection with any Permitted Convertible Debt Financing and substantially concurrently with any purchase by Borrower of a related Permitted Bond Hedge Transaction and as may be amended in accordance with its terms; provided that (x) that the terms, conditions and covenants of each such call option transaction are customary for agreements of such type, as determined in good faith by the board of directors of Borrower or a committee thereof and (y) such call option transaction would be classified as an equity instrument in accordance with GAAP.

"Person" means any individual, sole proprietorship, partnership, joint venture, trust, unincorporated organization, association, corporation, limited liability company, institution, other entity or government.

"Pledge Agreement" means the Pledge Agreement dated as of the Closing Date between Borrower and Agent, as the same may from time to time be amended, restated, modified or otherwise supplemented.

"Principal Stock Exchange" means the NASDAQ or, if the common Equity Interests are not listed on the NASDAQ, the principal national securities exchange or public quotation system on which the common Equity Interests are then listed for trading or quoted.

"Qualified Cash" means an amount equal to (a) the amount of Borrower's Cash held in accounts subject to an Account Control Agreement in favor of Agent *minus* (b) the aggregate amount of all outstanding Indebtedness or any other amounts owed by Borrower pursuant to the Thermo Fisher Agreement.

"Qualified Equity Interests" means any Equity Interests that are not Disqualified Equity Interests.

"Qualified Equity Issuance Net Proceeds" means the cumulative net proceeds in Cash (excluding any conversion of existing notes, share repurchases, or other holdbacks or discounts) received by Company as consideration for any (a) public or private sale or issuance of any Qualified Equity Interests of Company, (b) contribution to the equity capital of Company (other than in exchange for Disqualified Equity Interests), (c) sale or issuance of Indebtedness of Company (other than intercompany Indebtedness) that may be converted into or exchanged for Qualified Equity Interests of Company and which constitutes a Permitted Convertible Debt Financing, (d) Permitted Royalty Transaction, (e) sale or issuance of Subordinated Indebtedness, or (f) entry into a Permitted Out-License; provided that the amount of Cash received by Company is, (i) in the case of clauses (a) and (b) above, measured at the time made and without adjustment for subsequent changes in value, payable for the fair market value of sale, issuance or contribution and any other property received in connection with such sale, issuance or contribution, and paid by any Person that is not a Loan Party or an Affiliate thereof, and (ii) in the case of clause (c) above, the aggregate principal amount of Indebtedness sold or issued.

"Receivables" means (i) all of Borrower's Accounts, Instruments, Documents, Chattel Paper, Supporting Obligations, letters of credit, proceeds of any letter of credit, and Letter of Credit Rights, and (ii) all customer lists, software, and business records related thereto.

"Redemption Conditions" means, with respect to any cash payment in connection with a redemption or prepayment of any Permitted Convertible Debt, satisfaction of each of the following events: (a) no Default or Event of Default shall exist or result therefrom, and (b) both immediately before and after such redemption, the Borrower's Qualified Cash shall be no less than [**] percent ([**]%) of the Secured Obligations (inclusive of any Prepayment Charge and End of Term Charge that would be due and owing if the outstanding Term Loan Advances were prepaid at the time of measurement).

"Registration" means any registration, authorization, approval, license, permit, clearance, certificate, and exemption issued or allowed by the FDA or state pharmacy licensing authorities (including, without limitation, new drug applications, Biologics License Applications, abbreviated new drug applications, investigational new drug applications, pricing and reimbursement approvals, labelling approvals or their foreign equivalent, and wholesale distributor permits).

"Required Lenders" means at any time, the holders of more than fifty percent (50%) of the sum of the aggregate unpaid principal amount of the Term Loans then outstanding. "Sanctioned Country" means, at any time, a country or territory which is the subject or target of any Sanctions.

"Sanctioned Person" means, at any time, (a) any Person listed in any Sanctions-related list of designated Persons maintained by the Office of Foreign Assets Control of the U.S. Department of the Treasury or the U.S. Department of State, or by the United Nations Security Council, the European Union or any EU member state, (b) any Person operating, organized or resident in a Sanctioned Country or (c) any Person controlled by any such Person.

"Sanctions" means economic or financial sanctions or trade embargoes imposed, administered or enforced from time to time by (a) the U.S. government, including those administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury or the U.S. Department of State, or (b) the United Nations Security Council, the European Union or His Majesty's Treasury of the United Kingdom.

"SBA Funding Date" means each date on which a Lender which is an SBIC funds any portion of the Term Loans.

"Secured Obligations" means Borrower's obligations under this Agreement and any Loan Document, including any obligation to pay any amount now owing or later arising.

"Subordinated Indebtedness" means Indebtedness subordinated to the Secured Obligations in amounts and on terms and conditions reasonably satisfactory to Agent and subject to a subordination agreement in form and substance satisfactory to Agent in its sole discretion.

"Subsidiary" means an entity, whether a corporation, partnership, limited liability company, joint venture or otherwise, in which Borrower owns or controls, either directly or indirectly, fifty percent (50%) or more of the outstanding voting securities, including each entity listed on Schedule 1.

"Taxes" means all present or future taxes, levies, imposts, duties, deductions, withholdings (including backup withholding), assessments, fees or other charges imposed by any Governmental Authority, including any interest, additions to tax or penalties applicable thereto.

"Term Loan" means any Term Loan Advance made under this Agreement.

"Term Loan Advance" means each Tranche 1 Advance, Tranche 2 Advance, Tranche 3 Advance, Tranche 4 Advance, Tranche 5 Advance and any other funds advanced under Section 2.2(a).

"Thermo Fisher Agreement" means each Extended Payment Schedule Agreement entered into by and between Borrower and Thermo Fisher Financial Services, Inc., a Delaware corporation, which agreement shall be in a form reasonably satisfactory to Agent; provided that Agent and Lenders understand and agree that Borrower may enter into an Extended Payment Schedule Agreement on up to a monthly basis without Agent approval at any time after Agent provides its initial approval, in writing, of the form of Extended Payment Schedule Agreement, so long as the form used is identical in all respects to the initially approved form. For the avoidance of doubt, any change to the initially approved form of Extended Payment Schedule Agreement shall require Agent's prior written approval.

"Thermo Fisher Installment Payments" means those certain installment payments made by Borrower pursuant to any Thermo Fisher Agreement when due and payable under the terms of such Thermo Fisher Agreement; provided that the maximum aggregate unpaid amount of such installment payments shall not at any time exceed Thirty-Five Million Dollars ($35,000,000).

"Trademark License" means any written agreement granting any right to use any Trademark or Trademark registration, now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest.

"Trademarks" means all trademarks (registered, common law or otherwise) and any applications in connection therewith, including registrations, recordings and applications in the United States Patent and Trademark Office or in any similar office or agency of the United States of America, any State thereof or any other country or any political subdivision thereof.

"Trading Day" means any day on which (a) there is no Market Disruption Event and (b) the Principal Stock Exchange is open for trading; provided that a "Trading Day" only includes those days that have a scheduled closing time of 4:00 p.m. (Eastern time) or the then standard closing time for regular trading on the relevant exchange or trading system.

"Tranche" means the Tranche 1 Advance, Tranche 2 Advance, Tranche 3 Advance, Tranche 4 Advance and/or Tranche 5 Advance, as applicable.

"U.S. Person" means any Person that is a "United States person" as defined in Section 7701(a)(30) of the Code.

"UCC" means the Uniform Commercial Code as the same is, from time to time, in effect in the State of New York; provided, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection or priority of, or remedies with respect to, Agent's Lien on any Collateral is governed by the Uniform Commercial Code as the same is, from time to time, in effect in a jurisdiction other than the State of New York, then the term "UCC" shall mean the Uniform Commercial Code as in effect, from time to time, in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority or remedies and for purposes of definitions related to such provisions.

1.2 The following terms are defined in the Sections or subsections referenced opposite such terms:

Defined Term	Section

1940 Act	5.6(b)
Act	8.1
Agent	Preamble
Amortization Date	Exhibit K
Approval Milestone I	Exhibit K
Approval Milestone II	Exhibit K
Assignee	11.14
At-the-Market Offering	Exhibit K
Borrower	Preamble
Claims	11.11(a)
Collateral	3.1
Commercial Milestone	Exhibit K
Company	Preamble
Confidential Information	11.13
Current Company IP	5.10(a)
Data Milestone I	Exhibit K
Data Milestone II	Exhibit K
Due Diligence Fee	Exhibit K
End of Term Charge	Exhibit K
End of Term Charge Percentage	Exhibit K
Event of Default	9
Excluded Assets	3.2
Financial Statements	7.1
Financing Milestone	Exhibit K
First Interest Only Extension Conditions	Exhibit K
Indemnified Person	6.3
Information	5.7
Initial Facility Charge	Exhibit K
Initial Minimum Cash Test Date	Exhibit K
Initial Minimum Revenue Test Date	Exhibit K
Initial Revenue Trigger Test Date	Exhibit K
Lenders	Preamble
Liabilities	6.3
Maximum Rate	2.3
Maximum Term Loan Amount	Exhibit K
Minimum Advance Amount	Exhibit K
Participant Register	11.8
Payment Date	2.2(e)

Permitted Convertible Debt Financing Payments	7.24
Permitted Segregated Royalty Account	Clause (xvi) of the definition of "Permitted Liens"
Prepayment Charge	Exhibit K
Prime Rate	Exhibit K
Publicity Materials	11.19
Register	11.7
Second Interest Only Extension Conditions	Exhibit K
Subsequent Financing	Exhibit K
Subsequent Tranche Facility Charge	Exhibit K
Surviving Obligations	Definition of "Payment in Full"
Term Commitment	Exhibit K
Term Loan Interest Rate	Exhibit K
Term Loan Maturity Date	Exhibit K
Tranche 1 Advance	2.2(a)
Tranche 1 Commitment	Exhibit K
Tranche 2 Advance	2.2(a)
Tranche 2 Commitment	Exhibit K
Tranche 2 Milestone	Exhibit K
Tranche 3 Advances	2.2(a)
Tranche 3 Commitment	Exhibit K
Tranche 3 Commitment Period	Exhibit K
Tranche 3 Milestone	Exhibit K
Tranche 4 Advances	2.2(a)
Tranche 4 Commitment	Exhibit K
Tranche 4 Commitment Period	Exhibit K
Tranche 4 Milestone	Exhibit K
Tranche 5 Commitment	Exhibit K
Tranche 5 Commitment Period	Exhibit K
Transfer	7.8

1.3 Unless otherwise specified, all references in this Agreement or any Annex or Schedule hereto to a "Section," "subsection," "Exhibit," "Annex," or "Schedule" shall refer to the corresponding Section, subsection, Exhibit, Annex, or Schedule in or to this Agreement. Unless otherwise specifically provided herein, any accounting term used in this Agreement or the other Loan Documents shall have the meaning customarily given such term in accordance with GAAP as in effect on the date hereof, and all financial computations hereunder shall be computed in accordance with GAAP as in effect on the date hereof, consistently applied. Unless otherwise defined herein or in the other Loan Documents, terms that are used herein or in the other Loan Documents and defined in the UCC shall have the meanings given to

them in the UCC. For all purposes under the Loan Documents, in connection with any Division or plan of Division under Delaware law (or any comparable event under a different jurisdiction's laws): (a) if any asset, right, obligation or liability of any Person becomes the asset, right, obligation or liability of a different Person, then it shall be deemed to have been transferred from the original Person to the subsequent Person and (b) if any new Person comes into existence, such new Person shall be deemed to have been organized on the first date of its existence by the holders of its Equity Interests at such time.

1.4 If at any time any change in GAAP would affect the computation of any financial requirement set forth in any Loan Document, and either Borrower or the Required Lenders shall so request, Agent, Lenders and Borrower shall negotiate in good faith to amend such requirement to preserve the original intent thereof in light of such change in GAAP; provided that, until so amended, such requirement shall continue to be computed in accordance with GAAP prior to such change.

1.5 Any reference in any Loan Document to a merger, transfer, consolidation, amalgamation, consolidation, assignment, sale, disposition or transfer, or similar term, shall be deemed to apply to a Division of or by a limited liability company, or an allocation of assets to a series of a limited liability company (or the unwinding of such a Division or allocation), as if it were a merger, transfer, consolidation, amalgamation, consolidation, assignment, sale or transfer, or similar term, as applicable, to, of or with a separate Person. Any Division of a limited liability company shall constitute a separate Person under the Loan Documents (and each Division of any limited liability company that is a Subsidiary, joint venture or any other like term shall also constitute such a Person or entity) on the first date of its existence. In connection with any Division, if any asset, right, obligation or liability of any Person becomes the asset, right, obligation or liability of a different Person, then such asset shall be deemed to have been transferred from the original Person to the subsequent Person.

1.6 Notwithstanding anything in the definition of GAAP to the contrary, any obligations under a lease that is not (or would not be) a capital lease under GAAP as in effect prior to giving effect to FASB Accounting Standards Update No. 2016-02, Leases, shall not be treated as a capital lease solely as a result of the adoption of changes in GAAP.

SECTION 2. THE LOAN

2.1 [Reserved]

2.2 Term Loan Advances.

(a) Advances.

(i) Tranche 1. Subject to the terms and conditions of this Agreement, on the Closing Date, Lenders shall severally (and not jointly) make, and Borrower agrees to draw, a Term Loan Advance in an aggregate principal amount equal to the Tranche 1 Commitment (such Term Loan Advance, the "Tranche 1 Advance").

(ii) Tranche 2. Subject to the terms and conditions of this Agreement and Borrower's achievement of Data Milestone I, on the First Amendment Closing Date, Lenders shall severally (and not jointly) make, and Borrower agrees to draw, a Term Loan Advance in an aggregate principal amount equal to the Tranche 2 Commitment (such Term Loan Advance, the "Tranche 2 Advance").

(iii) Tranche 3. Subject to the terms and conditions of this Agreement, Borrower may request, and the Lenders shall severally (and not jointly) make, in each case,

at any time during the Tranche 3 Commitment Period, up to three additional Term Loan Advances in minimum increments of the Minimum Advance Amount (or if less, the remaining amount of Term Loan Advances available to be drawn pursuant to this Section 2.2(a)(iii)) in an aggregate principal amount up to the Tranche 3 Commitment (such Term Loan Advances, the "Tranche 3 Advances").

(iv) Tranche 4. Subject to the terms and conditions of this Agreement, Borrower may request, and the Lenders shall severally (and not jointly) make, in each case, at any time during the Tranche 4 Commitment Period, up to three additional Term Loan Advances in minimum increments of the Minimum Advance Amount (or if less, the remaining amount of Term Loan Advances available to be drawn pursuant to this Section 2.2(a)(iv)) in an aggregate principal amount up to the Tranche 4 Commitment (such Term Loan Advances, the "Tranche 4 Advances").

(v) Tranche 5. Subject to the terms and conditions of this Agreement, Borrower may request, and the Lenders shall severally (and not jointly) make, in each case, at any time during the Tranche 5 Commitment Period, and conditioned on approval by Lenders' investment committee in its sole and unfettered discretion, one or more additional Term Loan Advances in minimum increments of the Minimum Advance Amount (or if less, the remaining amount of Term Loan Advances available to be drawn pursuant to this Section 2.2(a)(v)) in an aggregate principal amount up to the Tranche 5 Commitment (such Term Loan Advances, the "Tranche 5 Advances").

(b) Maximum Term Loan Amount. The aggregate outstanding Term Loan Advances shall not exceed the Maximum Term Loan Amount. Each Term Loan Advance of each Lender shall not exceed its respective Term Commitment. After repayment, no Term Loan Advance (or any portion thereof) may be reborrowed.

(c) Advance Request. To obtain a Term Loan Advance, Borrower shall complete, sign and deliver an Advance Request (at least one (1) Business Day before the Closing Date and at least five (5) Business Days before each Advance Date other than the Closing Date) to Agent. Lenders shall fund the Term Loan Advance in the manner requested by the Advance Request provided that each of the conditions precedent set forth in Section 4 and applicable to such Term Loan Advance is satisfied as of the requested Advance Date. The proceeds of any Term Loan Advance shall be deposited into an account that is subject to an Account Control Agreement.

(d) Interest.

(i) Term Loan Interest Rate. The principal balance shall bear interest thereon from such Advance Date at the Term Loan Interest Rate, based on a year consisting of three hundred sixty (360) days, with interest computed daily based on the actual number of days elapsed. The Term Loan Interest Rate will float and change on the day the Prime Rate changes from time to time.

(e) Payment. Borrower will pay accrued but unpaid interest on each Term Loan Advance on the first Business Day of each month (each such date, a "Payment Date"), beginning the month after the Advance Date. Borrower shall repay the aggregate principal balance of the Term Loan Advances that is outstanding on the day immediately preceding the Amortization Date, in equal monthly installments of principal and interest (mortgage style) beginning on the Amortization Date and continuing on the first Business Day of each month thereafter until Payment in Full. The entire principal balance of the Term Loan Advances and all accrued but unpaid interest

hereunder, shall be due and payable on the Term Loan Maturity Date; provided, that if the Term Loan Maturity Date is not a Business Day, the Term Loan Maturity Date shall be the immediately subsequent Business Day. Borrower shall make all payments under this Agreement without setoff, recoupment or deduction and regardless of any counterclaim or defense, other than Taxes, which shall be governed by Addendum 1. If a payment hereunder becomes due and payable on a day that is not a Business Day, the due date thereof shall be the immediately subsequent Business Day. Agent or Lenders will initiate debit entries to Borrower's account as authorized on the ACH Authorization (i) on each Payment Date of all periodic obligations payable to Lenders under each Term Loan Advance outstanding and (ii) reasonable and documented out-of-pocket legal fees and costs incurred by Agent or Lenders that is reimbursable by Borrower in accordance with Section 11.12; provided that, with respect to clause (i) above, in the event that Lenders or Agent informs Borrower that Lenders will not initiate a debit entry to Borrower's account for a certain amount of the periodic obligations due on a specific Payment Date, Borrower shall pay to Lenders, such amount of periodic obligations in full in immediately available funds on such Payment Date; provided, further, that, with respect to clause (i) above, if Lenders or Agent informs Borrower that Lenders will not initiate a debit entry as described above later than the date that is three (3) Business Days prior to such Payment Date, Borrower shall pay to Lenders such amount of periodic obligations in full in immediately available funds on the date that is three (3) Business Days after the date on which Lenders or Agent notifies Borrower of such; provided, further, that, with respect to clause (ii) above, in the event that Lenders or Agent informs Borrower that Lenders will not initiate a debit entry to Borrower's account for specified reasonable and documented out-of-pocket legal fees and costs incurred by Agent or Lenders, Borrower shall pay to Lenders such amount in full in immediately available funds within three (3) Business Days after the date on which Lenders or Agent notifies Borrower of such.

2.3 Maximum Interest. Notwithstanding any provision in this Agreement or any other Loan Document to the contrary, it is the parties' intent not to contract for, charge or receive interest at a rate that is greater than the maximum rate permissible by law that a court of competent jurisdiction shall deem applicable hereto (which under the laws of the State of New York shall be deemed to be the laws relating to permissible rates of interest on commercial loans) (the "Maximum Rate"). If a court of competent jurisdiction shall finally determine that Borrower has actually paid to Lenders an amount of interest in excess of the amount that would have been payable if all of the Secured Obligations had at all times borne interest at the Maximum Rate, then such excess interest actually paid by Borrower shall be applied as follows: first, to the payment of the Secured Obligations consisting of the outstanding principal; second, after all principal is repaid, to the payment of Lenders' accrued interest, costs, expenses, professional fees and any other Secured Obligations then due and payable hereunder; and third, after all Secured Obligations are repaid (other than inchoate indemnity obligations), the excess (if any) shall be refunded to Borrower.

2.4 Default Interest. In the event any payment is not paid on the scheduled payment date, an amount equal to four percent (4%) of such past due amount shall be payable on demand. In addition, upon the occurrence and during the continuation of an Event of Default hereunder, all outstanding Secured Obligations, including principal, interest, compounded interest, and professional fees, shall bear interest at a rate per annum equal to the rate set forth in Section 2.2(d) plus four percent (4%) per annum. In the event any interest is not paid when due hereunder, delinquent interest shall be added to principal and shall bear interest on interest, compounded at the rate set forth in Section 2.2(d) or 2.4, as applicable.

2.5 Prepayment. At its option, Borrower may prepay all or a portion of the outstanding Advances by paying the entire principal balance (or such portion thereof) all accrued and unpaid interest thereon, all unpaid Lender's fees and expenses then due and payable hereunder accrued to

the date of the repayment (including, without limitation, the portion of the End of Term Charge applicable to the aggregate original principal amount of the Term Loan Advances being prepaid in accordance with Section 2.6(a)), together with a Prepayment Charge with respect to the outstanding principal amount of such Advance amount being so prepaid. Borrower agrees that the Prepayment Charge is a reasonable calculation of Lenders' lost profits in view of the difficulties and impracticality of determining actual damages resulting from an early repayment of the Advances. Borrower shall prepay the outstanding amount of all principal and accrued interest through the prepayment date and the Prepayment Charge upon the occurrence of a Change in Control or any other prepayment hereunder. Notwithstanding the foregoing, Agent and Lenders agree to waive the Prepayment Charge if Agent and Lenders (in their sole and absolute discretion) agree in writing to refinance the Advances prior to the Term Loan Maturity Date. Any amounts paid under this Section shall be applied by Agent to the then unpaid amount of any outstanding Secured Obligations (including principal and interest) in such order and priority as Agent may choose in its sole discretion. For the avoidance of doubt, if a payment hereunder becomes due and payable on a day that is not a Business Day, the due date thereof shall be the immediately subsequent Business Day.

2.6 End of Term Charge.

(a) On any date that Borrower partially prepays the outstanding Secured Obligations pursuant to Section 2.5, Borrower shall pay Lenders a charge equal to the product of the End of Term Charge Percentage *multiplied* by the principal amount of such Term Loan Advances being prepaid.

(b) On the earliest to occur of (i) the Term Loan Maturity Date, (ii) Payment in Full or (iii) the date that the outstanding Secured Obligations become due and payable, Borrower shall pay Lenders a charge equal to the End of Term Charge.

(c) Notwithstanding the required payment date of such End of Term Charge, the applicable pro rata portion of the End of Term Charge shall be deemed earned by Lenders as of each date that an applicable Term Loan Advance is made. For the avoidance of doubt, if a payment hereunder becomes due and payable on a day that is not a Business Day, the due date thereof shall be the immediately subsequent Business Day.

2.7 Pro Rata Treatment. Each payment (including prepayment) on account of any fee and any reduction of the Term Loan Advances shall be made pro rata according to the Term Commitments of the relevant Lender.

2.8 Taxes; Increased Costs. Borrower, Agent and Lenders each hereby agree to the terms and conditions set forth on Addendum 1 attached hereto.

2.9 Treatment of Prepayment Charge and End of Term Charge. Borrower agrees that any Prepayment Charge and any End of Term Charge payable shall be presumed to be the liquidated damages sustained by each Lender as the result of the early termination, and Borrower agrees that it is reasonable under the circumstances currently existing and existing as of the Closing Date. The Prepayment Charge and the End of Term Charge shall also be payable in the event the Secured Obligations (and/or this Agreement) are satisfied or released by foreclosure (whether by power of judicial proceeding), deed in lieu of foreclosure, or by any other means. Each Loan Party expressly waives (to the fullest extent it may lawfully do so) the provisions of any present or future statute or law that prohibits or may prohibit the collection of the foregoing Prepayment Charge and End of Term Charge in connection with any such acceleration. Borrower agrees (to the fullest extent that each may lawfully do so): (a) each of the Prepayment Charge and the End of Term Charge is

reasonable and is the product of an arm's length transaction between sophisticated business people, ably represented by counsel; (b) each of the Prepayment Charge and the End of Term Charge shall be payable notwithstanding the then prevailing market rates at the time payment is made; (c) there has been a course of conduct between Lenders and Borrower giving specific consideration in this transaction for such agreement to pay the Prepayment Charge and the End of Term Charge as a charge (and not interest) in the event of prepayment or acceleration; and (d) Borrower shall be estopped from claiming differently than as agreed to in this Section. Borrower expressly acknowledges that its agreement to pay each of the Prepayment Charge and the End of Term Charge to Lenders as herein described was on the Closing Date and continues to be a material inducement to Lenders to provide the Term Loan Advances.

2.10 Due Diligence Fee. Borrower agrees that the Due Diligence Fee has been paid to Agent and received by Agent prior to the Closing Date, and shall be deemed fully earned on such date regardless of the early termination of this Agreement. The Agent agrees that the Due Diligence Fee shall be applied in its entirety on the Closing Date to towards the Lenders' non-legal transaction costs and diligence expenses.

SECTION 3. SECURITY INTEREST

3.1 Grant of Security Interest. As security for the prompt and complete payment when due (whether on the payment dates or otherwise) of all the Secured Obligations, each Borrower grants to Agent a security interest in all of such Borrower's right, title, and interest in, to and under all of such Borrower's personal property and other assets including without limitation the following (except as set forth herein) whether now owned or hereafter acquired (collectively, excluding the Excluded Assets, the "Collateral"): (a) Receivables; (b) Equipment; (c) Fixtures; (d) General Intangibles; (e) Inventory; (f) Investment Property; (g) Deposit Accounts; (h) Cash; (i) Goods; and all other tangible and intangible personal property of such Borrower whether now or hereafter owned or existing, leased, consigned by or to, or acquired by, Borrower and wherever located, and any of such Borrower's property in the possession or under the control of Agent; and, to the extent not otherwise included, all Proceeds of each of the foregoing and all accessions to, substitutions and replacements for, and rents, profits and products of each of the foregoing.

3.2 Notwithstanding the broad grant of the security interest set forth in Section 3.1, above, the Collateral shall not include (a) any "intent to use" trademarks at all times prior to the first use thereof, whether by the actual use thereof in commerce, the recording of a statement of use with the United States Patent and Trademark Office or otherwise, provided, that upon submission and acceptance by the United States Patent and Trademark Office of an amendment to allege use of an intent-to-use trademark application pursuant to 15 U.S.C. Section 1060(a) (or any successor provision) such intent-to-use application shall constitute Collateral, (b) nonassignable licenses or contracts, which by their terms require the consent of the licensor thereof or another party (but only to the extent such prohibition on transfer is enforceable under applicable law, including, without limitation, Sections 9-406, 9-407 and 9-408 of the UCC), (c) any Excluded Account, (d) any assets as to which Agent in its reasonable discretion shall determine that the costs and burdens of obtaining or perfecting a security interest therein substantially outweigh the benefit to the Lenders of the security afforded thereby (including, without limitation, vehicles and other assets subject to a certificate of title), (e) more than 65% of the issued and outstanding shares of capital stock which entitle the holder thereof to vote for directors or any other matter of any Foreign Subsidiary, which is an Excluded Subsidiary, formed after the Closing Date, solely to the extent Borrower has provided Agent with evidence satisfactory to Agent that the pledge of more than 65% of such voting stock of such Subsidiary could reasonably be expected to result in a material adverse tax consequence to Borrower, and solely for as long as such consequence may result, such portion of such voting stock

of such Subsidiary, if excluded from the Collateral, would avoid such material adverse tax consequence (it being understood that in the case of any Foreign Subsidiary whose ownership does not satisfy the holding period requirement set forth in Section 246(c)(5) of the Code, not more than 65% of such Foreign Subsidiary's stock shall be required to be pledged until the holding period is satisfied), (f) property for which the granting of a security interest therein is contrary to applicable law, rule or regulation, provided that upon the cessation of any such restriction or prohibition, such property shall automatically be included in the Collateral, (g) any cash collateral deposit subject to a Permitted Lien hereunder, provided that upon the termination and release of such cash collateral, such property shall automatically be included in the Collateral, (h) any lease, license or other agreement and any property subject thereto on the Closing Date or on the date of the acquisition of such property (other than any property acquired by a Loan Party subject to any such contract or other agreement to the extent such contract or other agreement was incurred in contemplation of such acquisition) to the extent that a grant of a security interest therein to secure the Secured Obligations would violate or invalidate such lease, license, contract or agreement or create a right of termination in favor of any other party thereto (other than Borrower, any other Loan Party or any Subsidiary) (but (A) only to the extent such prohibition is enforceable under applicable law and (B) other than to the extent that any such term would be rendered ineffective pursuant to Sections 9-406, 9-408 or 9-409 (or any other Section) of Article 9 of the UCC), (i) Equipment or software or other intellectual property (and the products and proceeds thereof) subject to Permitted Liens of the type described in clause (vii) of the definition of Permitted Liens, but only to the extent and for so long as the agreements under which the equipment is financed prohibit granting a security interest therein to Agent and letter-of-credit rights not constituting supporting obligations of other Collateral and (j) any commercial tort claim (as defined in the UCC that does not exceed One Million Dollars ($1,000,000) (collectively, the "Excluded Assets").

3.3 Notwithstanding any of the foregoing or anything in this Agreement or any other Loan Document to the contrary, no perfection steps shall be required with respect to any Excluded Assets.

3.4 Upon Payment in Full, all security interest in the Collateral granted under this Agreement shall immediately terminate and all rights on the Collateral shall revert to Borrower with the need for any other action by any Person. Agent shall execute such documents and take such other steps as are reasonably necessary for Borrower to accomplish the foregoing, all at Borrower's sole cost and expense.

SECTION 4. CONDITIONS PRECEDENT TO LOAN

The obligations of Lenders to make the Loan hereunder are subject to the satisfaction by Borrower (or waiver by the Lenders) of the following conditions:

4.1 Initial Advance. On or prior to the Closing Date, Borrower shall have delivered to Agent the following:

(a) duly executed copies of the Loan Documents to be entered into on the Closing Date, and all other documents and instruments reasonably required by Agent to be delivered on or prior to the Closing Date to effectuate the transactions contemplated hereby or to create and perfect the Liens of Agent with respect to all Collateral, in all cases in form and substance reasonably acceptable to Agent;

(b) duly executed Account Control Agreement with respect to the Funding Account;

(c) a legal opinion of Borrower's counsel in form and substance reasonably acceptable to Agent;

(d) copy of resolutions of each Borrower's Board of Directors, certified by an officer of such Borrower, (i) evidencing approval of the Loan and other transactions evidenced by the Loan Documents, (ii) authorizing a specified person or persons to execute the Loan Documents to which it is a party on its behalf, (iii) authorizing a specified person or persons, on its behalf, to sign and/or dispatch all documents and notices (including, if relevant, any Advance Request or other relevant notice) to be signed and/or dispatched by it under or in connection with the Loan Documents to which it is a party, and (iv) acknowledging that the Board of Directors are acting for a proper purpose and that the Loan Documents are in the best interests of that Borrower and for its commercial benefit;

(e) certified copies of the Charter of Borrower, certified by the Secretary of State of the applicable jurisdiction of organization and the other Organizational Documents, as amended through the Closing Date, of Borrower;

(f) a certificate of good standing for Borrower from its jurisdiction of organization and similar certificates from all other jurisdictions in which it does business and where the failure to be qualified could have a Material Adverse Effect;

(g) certified copies, dated as of a recent date, of searches for financing statements filed in the central filing office of the State of Delaware, accompanied by written evidence (including any UCC termination statements) that the Liens on any Collateral indicated in any such financing statements either constitute Permitted Liens or have been or, in connection with the initial Term Loan Advance, will be terminated or released;

(h) payment of the Due Diligence Fee, Initial Facility Charge and reimbursement of Agent's and Lenders' current expenses reimbursable pursuant to this Agreement, which amounts may be deducted from the initial Advance;

(i) a duly executed copy of the Perfection Certificate and each exhibit and addendum thereto;

(j) subject to Section 6.2, all certificates of insurance required hereunder;

(k) [reserved];

(l) all reports, declarations and forms required by the SBA, including but not limited to SBA 652, SBA 1031 and SBA 480; and

(m) such other documents as Agent may reasonably request.

4.2 All Advances. On each Advance Date:

(a) Agent shall have received (i) an Advance Request for the relevant Advance as required by Section 2.2(c), duly executed by Borrower's Chief Executive Officer or Chief Financial Officer, and (ii) any other documents Agent may reasonably request in its good faith business discretion so long as such request does not result in the intentional delay or denial of the relevant Advance;

(b) The representations and warranties set forth in this Agreement shall be true and correct in all material respects on and as of the applicable Advance Date with the same effect as though made on and as of such date, except to the extent such representations and warranties expressly relate to an earlier date;

(c) [reserved];

(d) With respect to any Advance (other than the Tranche 1 Advance) made available on such Advance Date, the Loan Parties shall have paid, or shall concurrently with such Advance pay, the Subsequent Tranche Facility Charge (which amount may be deducted from such Tranche) applicable to such Advance; and

(e) Each Advance Request shall be deemed to constitute a representation and warranty by Borrower on the relevant Advance Date as to the matters specified in Section 4.2(b) and Section 4.4 and as to the matters set forth in the Advance Request.

4.3 [Reserved.]

4.4 No Default. As of the Closing Date and at the time of and immediately after each Advance Date, (i) no Default or Event of Default shall have occurred and be continuing and (ii) no event that has had or could reasonably be expected to have a Material Adverse Effect has occurred and is continuing.

4.5 Post-Closing Conditions Subsequent. Borrower shall satisfy each of the conditions subsequent to the Closing Date specified in this Section 4.5 to the satisfaction of Agent, in each case, by no later than the date specified for such condition below (or such later date as Agent shall agree in its sole discretion):

(a) Within thirty (30) days of the Closing Date (or such longer period of time as agreed to by Agent in writing in its sole discretion), use commercially reasonable efforts to deliver to the Agent duly executed landlord consents for its (i) chief executive office or its principal place of business and (ii) offices or business locations, including warehouses, containing in excess of Two Million Dollars ($2,000,000) of Borrower's assets or property (other than offices, business locations or warehouses holding primarily (i) works-in-progress, raw materials or otherwise in the supply chain for commercial manufacturing or sale of Borrower Products, (ii) inventory or other goods in transit, or (iii) assets (other than equipment) in connection with clinical and pre-clinical studies, including contract manufacturing organizations, distribution service firms, contract research organizations, clinical sites, clinical investigators and other institutions);

(b) Within thirty (30) days of the Closing Date (or such longer period of time as agreed to by Agent in writing in its sole discretion), use commercially reasonable efforts to deliver to the Agent duly executed bailee agreements for any bailee location holding a portion of Borrower's assets or property valued, individually or in the aggregate, in excess of Three Million Dollars ($3,000,000) (other than bailees or other third parties in possession of: (i) works-in-progress, raw materials or otherwise in the supply chain for commercial manufacturing or sale of Borrower Products, (ii) inventory or other goods in transit, or (iii) assets (other than equipment) in connection with clinical and pre-clinical studies, including contract manufacturing organizations, distribution service firms, contract research organizations, clinical sites, clinical investigators and other institutions);

(c) Within three (3) days of the Closing Date (or such longer period of time as agreed to by Agent in writing in its sole discretion), deliver to Agent duly executed Account Control Agreement(s) with respect to each Deposit Account and account holding Investment Property (other than the Funding Account and any Excluded Account) maintained by Borrower or any Subsidiary (other than the MSC Subsidiary);

(d) Within thirty (30) days of the Closing Date (or such longer period of time as agreed to by Agent in writing in its sole discretion), (i) evidence of cyber liability insurance coverage and (ii) commercial property insurance certificates and endorsements showing Agent as lender's loss payable, as required pursuant to Section 6.2 hereunder; and

(e) Within ten (10) days of the Closing Date (or such longer period of time as agreed to by Agent in writing in its sole discretion), Borrower shall cause the shares of common stock of the MSC Subsidiary and that are the subject of the pledged collateral under the Pledge Agreement to be certificated and the original certificate and power (undated and executed in blank) to be delivered to Agent.

SECTION 5. REPRESENTATIONS AND WARRANTIES OF BORROWER

Borrower represents and warrants that:

5.1 Corporate Status; Execution and Delivery; Binding Effect. Each Borrower is a corporation duly organized, legally existing and in good standing under the laws of its jurisdiction of incorporation, and is duly qualified as a foreign corporation, limited liability company or partnership, as the case may be, in all jurisdictions in which the nature of its business or location of its properties require such qualifications and where the failure to be qualified could reasonably be expected to have a Material Adverse Effect. Borrower's present name, former names (if any), locations, place of formation, tax identification number, organizational identification number and other information are correctly set forth in Exhibit B, as may be updated by Borrower in a written notice (including any Compliance Certificate) provided to Agent after the Closing Date in accordance with this Agreement. This Agreement has been, and each other Loan Document, when delivered hereunder, will have been, duly executed and delivered by the Borrower. This Agreement constitutes, and each other Loan Document when so delivered will constitute, a legal, valid and binding obligation of the Borrower, enforceable against the Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, receivership, moratorium or other laws affecting creditors' rights generally and by general principles of equity.

5.2 Collateral. Borrower owns or otherwise has the rights to use the Collateral, free of all Liens, except for Permitted Liens. Borrower has the power and authority to grant to Agent a Lien in the Collateral as security for the Secured Obligations.

5.3 Consents. Borrower's execution, delivery and performance of this Agreement and all other Loan Documents to which it is a party, (i) have been duly authorized by all necessary action of Borrower in accordance with its Organizational Documents and applicable law, (ii) will not result in the creation or imposition of any Lien upon the Collateral, other than Permitted Liens, (iii) do not violate any provisions of (A) Borrower's Organizational Documents or (B) any material law, regulation, order, injunction, judgment, decree or writ to which Borrower is subject in any material respect and (iv) except as described on Schedule 5.3, do not violate any Material Agreement or require the consent or approval of any other Person or Governmental Authority which has not

already been obtained. The individual or individuals executing the Loan Documents are duly authorized to do so.

5.4 Material Adverse Effect. No event that has had or could reasonably be expected to have a Material Adverse Effect has occurred and is continuing. Borrower is not aware of any event or circumstance that is likely to occur that is reasonably expected to result in a Material Adverse Effect; provided that the occurrence of the following, individually, shall not, in and of itself, constitute a "Material Adverse Effect" hereunder: (i) the failure to achieve any Milestone, (ii) adverse results or delays with respect to, or the failure to achieve, any clinical or non-clinical trial goals or objectives, (iii) the denial, delay or limitation or qualification of approval of the FDA or other regulatory agency with respect to any proposed drug or other Borrower Products, or (iv) any revisions to or termination of a strategic alliance, joint venture, co-promotion, co-commercialization or co-development agreements or license arrangement maintained by Borrower so long as the same does not affect the ability of Borrower to perform or pay the Secured Obligations in accordance with the terms of the Loan Documents.

5.5 Actions Before Governmental Authorities. There are no actions, suits, claims, disputes or proceedings at law or in equity or by or before any Governmental Authority now pending or, to the knowledge of Borrower, threatened in writing against or affecting Borrower or its property, that is reasonably expected to result in a Material Adverse Effect.

5.6 Laws.

(a) Neither Borrower nor any of its Subsidiaries is in violation of any law, rule or regulation, or in default with respect to any judgment, writ, injunction or decree of any Governmental Authority to which Borrower or such Subsidiaries are subject, where such violation or default could reasonably be expected to result in a Material Adverse Effect. Borrower is not in default in any material respect under any provision of any agreement or instrument evidencing material Indebtedness or any other Material Agreement to which it is a party or by which it is bound.

(b) Neither Borrower nor any of its Subsidiaries is an "investment company," a company that would be an "investment company" except for the exclusion from the definition of "investment company" in Section 3(c) of the Investment Company Act of 1940, as amended (the "1940 Act"), or a company "controlled" by an "investment company" under the 1940 Act. Neither Borrower nor any of its Subsidiaries is engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Borrower and each of its Subsidiaries has complied in all material respects with the Federal Fair Labor Standards Act. Neither Borrower nor any of its Subsidiaries is a "holding company" or an "affiliate" of a "holding company" or a "subsidiary company" of a "holding company" as each term is defined and used in the Public Utility Holding Company Act of 2005. Neither Borrower's nor any of its Subsidiaries' properties or assets have been used by Borrower or such Subsidiary or, to Borrower's knowledge, by previous Persons, in disposing, producing, storing, treating, or transporting any hazardous substance other than in material compliance with applicable laws. Borrower and each of its Subsidiaries has obtained all material consents, approvals and authorizations of, made all material declarations or filings with, and given all material notices to, all Governmental Authorities that are necessary to continue in all material respects their respective businesses as currently conducted.

(c) None of Borrower, any of its Subsidiaries, nor (to the knowledge of any Loan Party) any of Borrower's or its Subsidiaries' Affiliates or any of their respective agents acting in

connection with the transactions contemplated by this Agreement is (i) in violation of any Anti-Terrorism Law, (ii) engaging in or conspiring to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding or attempts to violate, any of the prohibitions set forth in any Anti-Terrorism Law, or (iii) is a Blocked Person. None of Borrower, any of its Subsidiaries, or (to the knowledge of Borrower) any of their Affiliates or agents acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement, (x) conducts any business or engages in making or receiving any contribution of funds, goods or services to or for the benefit of any Blocked Person, or (y) deals in, or otherwise engages in any transaction relating to, any property or interest in property blocked pursuant to Executive Order No. 13224, any similar executive order or other Anti-Terrorism Law. None of the funds to be provided under this Agreement will be used, directly or indirectly, (a) for any activities in violation of any applicable anti-money laundering, economic sanctions and anti-bribery laws and regulations or (b) for any payment to any governmental official or employee, political party, official of a political party, candidate for political office, or anyone else acting in an official capacity, in order to obtain, retain or direct business or obtain any improper advantage, in violation of the United States Foreign Corrupt Practices Act of 1977, as amended.

5.7 Information Correct and Current. No written information, report, Advance Request, financial statement, exhibit or schedule furnished, by or on behalf of Borrower to Agent in connection with any Loan Document or included therein or delivered pursuant thereto (other than forward looking financial or business projections, or information of a general economic or industry nature) ("Information") contained as of the date such Information was furnished, when taken as a whole with all other Information given or furnished to Agent or any Lender, contains or will contain any material misstatement of fact or, when taken together with all other such information or documents, omitted, omits or will omit to state any material fact necessary to make the statements therein, in the light of the circumstances under which they were, are or will be made, not materially misleading at the time such statement was made or deemed made. Additionally, any and all financial or business projections or forecasts provided by Borrower to Agent under the Loan Documents, whether prior to or after the Closing Date, shall be (i) provided in good faith and based on assumptions believed to be reasonable at the time prepared (it being understood that such projections are subject to significant uncertainties and contingencies, many of which are beyond the control of any Loan Party, that no assurance is given that any particular projections will be realized and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results by a material amount) and (ii) the most current of such projections provided to and approved by Borrower's Board of Directors (other than management updates to years beyond the then-current fiscal year).

5.8 Tax Matters. Except as set forth on Schedule 5.8, (a) Borrower and its Subsidiaries have filed all federal and state income Tax returns and other material Tax returns that they are required to file (taking into account any timely filed extensions), (b) Borrower and its Subsidiaries have duly paid all federal and state income Taxes and other material Taxes or installments thereof that they are required to pay, except Taxes being contested in good faith by appropriate proceedings and for which Borrower and its Subsidiaries maintain adequate reserves in accordance with GAAP and which Taxes, if not paid would exceed [**] Dollars ($[**]), and (c) to the best of Borrower's knowledge, no proposed or pending Tax assessments, deficiencies, audits or other proceedings with respect to Borrower or any Subsidiary have had, or could reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect.

5.9 Intellectual Property Claims. Borrower is the sole owner of, or otherwise has the right to use, the Current Company IP. Except as described on Schedule 5.9 (as such schedule may be updated by Borrower in a written notice provided from time to time after the Closing Date) or

any Compliance Certificate, (i) each of the material Copyrights, Trademarks and Patents is valid and enforceable (other than with respect to expired or pending applications, including Patent applications), (ii) no material part of the Intellectual Property has been judged invalid or unenforceable, in whole or in part, and (iii) except as set forth in the Compliance Certificate delivered for the last month of the most recently ended fiscal quarter in accordance with Section 7.1(d), no claim has been made to Borrower that the ownership of or use of any material part of the Intellectual Property violates the rights of any third party. Exhibit C (which shall be automatically updated after the Closing Date upon Borrower providing the written notices required pursuant to Section 7.22) is a true, correct and complete list of each of Borrower's Patents, registered Trademarks, registered Copyrights, and Material IP Agreements under which Borrower licenses Intellectual Property from third parties (other than shrink-wrap software licenses, "off-the-shelf" licenses, open-source software), together with application or registration numbers, as applicable, owned by Borrower or any Subsidiary. Borrower is not in material breach of, nor has Borrower failed to perform any material obligations under, any of the foregoing contracts, licenses or agreements and, to Borrower's knowledge, no third party to any such contract, license or agreement is in material breach thereof or has failed to perform any material obligations thereunder.

5.10 Intellectual Property.

(a) A true, correct and complete list of each pending, registered or in-licensed Intellectual Property that, individually or taken together with any other such Intellectual Property, is material to the business of Borrower and its Subsidiaries, taken as a whole, relating to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of the Borrower Products, and is owned or co-owned by or exclusively licensed to Borrower or any of its Subsidiaries (collectively, the "Current Company IP"), including its name/title, current owner or co-owners (including ownership interest), registration, patent or application number, and registration or application date, issued or filed in the United States of America, is set forth on Schedule 5.10(a) or in the Compliance Certificate delivered for the last month of the most recently ended fiscal quarter in accordance with Section 7.1(d) (provided that such disclosure made in such Compliance Certificate shall not apply to a period covered by a prior Compliance Certificate and shall not cure any default arising from any false or misleading misrepresentations and warranties when made or when deemed made). Except as set forth on Schedule 5.10(a)(i) or in the Compliance Certificate delivered for the last month of the most recently ended fiscal quarter in accordance with Section 7.1(d), (A) to the knowledge of the Borrower, each item of owned Current Company IP is valid, subsisting and (other than with respect to expired or pending applications, including Patent applications) enforceable and no such item of Current Company IP has lapsed, expired, been cancelled or invalidated or become abandoned or unenforceable other than in the normal course of prosecuting Current Company IP or in connection with a Permitted Transfer, and (B) no written notice has been received challenging the inventorship or ownership, or relating to any lapse, expiration, invalidation, abandonment or unenforceability, of any such item of Current Company IP. Except as set forth on Schedule 5.10(a)(ii) or in the Compliance Certificate delivered for the last month of the most recently ended fiscal quarter in accordance with Section 7.1(d), (A) each such item of Current Company IP which is exclusively licensed from another Person is valid, subsisting and (other than with respect to expired or pending applications, including Patent applications) enforceable and no such item of Current Company IP has lapsed, expired, been canceled or invalidated, or become abandoned or unenforceable other than in the normal course of prosecuting Current Company IP, and (B) no written notice has been received challenging the inventorship or ownership, or relating to any lapse, expiration, invalidation, abandonment or unenforceability, of any such item of Current Company IP. To the knowledge of any Loan Party, there are no published valid Patents, Patent applications, articles or prior art references that would reasonably be expected to materially adversely affect the

exploitation of the Borrower Products. Except as set forth on Schedule 5.10(a)(x)-(y) or in the Compliance Certificate delivered for the last month of the most recently ended fiscal quarter in accordance with Section 7.1(d) (provided that such disclosure made in such Compliance Certificate shall not apply to a period covered by a prior Compliance Certificate and shall not cure any default arising from any false or misleading misrepresentations and warranties when made or when deemed made), (x) each Person who has or has had any rights in or to owned Current Company IP or any trade secrets owned by Borrower or any of its Subsidiaries, including each inventor named on the Patents within such owned Current Company IP filed by Borrower or any of its Subsidiaries has executed an agreement assigning directly or indirectly his, her or its entire right, title and interest in and to such owned Current Company IP and such trade secrets, and the inventions, improvements, discoveries, writings, works of authorship, information and other intellectual property embodied, described or claimed therein, to the stated owner thereof (or is expected to execute such agreement in due course), and (y) no such Person has any contractual or other obligation that would preclude or conflict with such assignment or the exploitation of the Borrower Products or entitle such Person to ongoing payments.

(b) (i) Borrower or any of its Subsidiaries possesses valid title to the Current Company IP for which it is listed as the owner or co-owner, as applicable, on Schedule 5.10(a); and (ii) there are no Liens on any Current Company IP (other than Permitted Liens).

(c) There are no material maintenance, annuity or renewal fees that are currently overdue beyond their allotted grace period for any of the Current Company IP which is owned or exclusively licensed to Borrower or any of its Subsidiaries, nor have any applications or registrations therefore, on account of such overdue fees, lapsed or become abandoned, been cancelled or expired in a manner that is not readily correctable. There are no material maintenance, annuity or renewal fees that are currently overdue beyond their allotted grace period for any of the Current Company IP which is non-exclusively licensed to Borrower or any of its Subsidiaries, nor have any material applications or registrations therefor lapsed or become abandoned, been canceled or expired.

(d) There are no unpaid fees or royalties under any Material Agreements concerning Current Company IP exclusively licensed to Borrower or any of its Subsidiaries ("Material IP Agreements"), that have become due, or are expected to become overdue and, each such Material IP Agreement is in full force and effect and is legal, valid, binding and enforceable in accordance with its respective terms, except as may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws relating to or limiting creditors' rights generally or by equitable principles relating to enforceability. Except as set forth on Schedule 5.10(d) or in the Compliance Certificate delivered for the last month of the most recently ended fiscal quarter in accordance with Section 7.1(d), neither Borrower nor any of its Subsidiaries, as applicable, is in breach of or default in any manner that could reasonably be expected to materially affect the Borrower Products under any Material Agreement to which it is a party or may otherwise be bound, and to the knowledge of each Loan Party no circumstances or grounds exist that would give rise to a claim of breach or right of rescission, termination, non-renewal, revision or amendment of any of the Material Agreements, including the execution, delivery and performance of this Agreement and the other Loan Documents.

(e) To Borrower's knowledge, no payments by Borrower or any of its Subsidiaries are due to any other Person in respect of the Current Company IP, other than pursuant to the Material IP Agreements and those fees payable to patent offices in connection with the prosecution and maintenance of the Current Company IP, any applicable taxes and associated attorney fees.

(f) Neither Borrower nor any of its Subsidiaries has undertaken or omitted to undertake any acts, and to the knowledge of each Loan Party no circumstance or grounds exist that would invalidate or reduce, in whole or in part, the enforceability of (i) the Current Company IP in any manner that could reasonably be expected to materially adversely affect the Borrower Products, or (ii) in the case of Current Company IP owned or co-owned or exclusively licensed by Borrower or any of its Subsidiaries, except as set forth on Schedule 5.10(f) or in the Compliance Certificate delivered for the last month of the most recently ended fiscal quarter in accordance with Section 7.1(d), Borrower's or Subsidiary's entitlement to own or license and exploit such Current Company IP.

(g) Except as described on Schedule 5.9 or in the Compliance Certificate delivered for the last month of the most recently ended fiscal quarter in accordance with Section 7.1(d), with respect to Current Company IP there is no requested, filed pending, decided or settled opposition, interference proceeding, reissue proceeding (other than reissue proceedings in the normal course of prosecuting Current Company IP), reexamination proceeding, inter-partes review proceeding, post-grant review proceeding, cancellation proceeding, injunction, litigation, paragraph IV patent certification or lawsuit under the Hatch-Waxman Act, hearing, investigation, complaint, arbitration, mediation, demand, International Trade Commission investigation, decree or any other dispute, disagreement, or claim, in each case alleged in writing to Borrower or any of its Subsidiaries (collectively referred to hereinafter as "Specified Disputes"), nor to the knowledge of any Loan Party, has any such Specified Dispute been threatened in writing, in each case challenging the legality, validity, enforceability or ownership of any Current Company IP, in each case that would have a Material Adverse Effect on the Borrower Products.

(h) In each case where an issued Patent within the Current Company IP is owned or co-owned by Borrower or any of its Subsidiaries by assignment, the assignment has been or will be in due course duly recorded with the U.S. Patent and Trademark Office.

(i) Except as set forth on Schedule 5.10(i) or in the Compliance Certificate delivered for the last month of the most recently ended fiscal quarter in accordance with Section 7.1(d) (provided that such disclosure made in such Compliance Certificate shall not apply to a period covered by a prior Compliance Certificate and shall not cure any default arising from any false or misleading misrepresentations and warranties when made or when deemed made), there are no pending or threatened (in writing) claims against Borrower or any of its Subsidiaries alleging (i) that any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of the Borrower Products in the United States of America infringes or violates (or in the past infringed or violated) the rights of any third parties in or to any valid intellectual property ("Third Party IP") or constitutes a misappropriation of (or in the past constituted a misappropriation of) any Third Party IP, or (ii) that any Current Company IP is invalid or unenforceable.

(j) Except as set forth on Schedule 5.10(j) or in the Compliance Certificate delivered for the last month of the most recently ended fiscal quarter in accordance with Section 7.1(d), the manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of the Borrower Products does not, to the knowledge of any Loan Party, infringe or violate any issued or registered Third Party IP (including any issued Patent within the Third Party IP) or constitute a misappropriation of any Third Party IP, in each case, in a manner that could reasonably be expected to materially adversely affect the exploitation of the Borrower Products.

(k) Except as set forth on Schedule 5.10(k) or in the Compliance Certificate delivered for the last month of the most recently ended fiscal quarter in accordance with Section 7.1(d), there are no settlements, covenants not to sue, consents, judgments, or orders which: (i) materially restrict the rights of Borrower or any of its Subsidiaries to use any Intellectual Property relating to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of the Borrower Products (in order to accommodate any Third Party IP or otherwise), or (ii) permit any third parties to use any Company IP in manner that would impair or hinder development of the Borrower Products.

(l) [Reserved].

(m) Borrower and each of its Subsidiaries have taken commercially reasonable measures customary in the biopharmaceutical industry to protect the confidentiality of all trade secrets owned by Borrower or any of its Subsidiaries or used or held for use by Borrower or any of its Subsidiaries, in each case relating to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of the Borrower Products.

(n) [Reserved].

(o) Except as described on Schedule 5.10(o) or in the Compliance Certificate delivered for the last month of the most recently ended fiscal quarter in accordance with Section 7.1(d), each Loan Party has all rights with respect to Intellectual Property necessary, other than any rights that would not be expected to cause a Material Adverse Effect, with respect to Current Company IP material in the operation or conduct of such Loan Party's business as currently conducted and proposed to be conducted by such Loan Party. Without limiting the generality of the foregoing, and in the case of Licenses, except for restrictions that are unenforceable under Article 9 of the UCC or are customary restrictions in exclusive Permitted Out-Licenses, each Loan Party has the right, to the extent required to operate such Loan Party's business, to freely transfer, license or assign Intellectual Property owned by such Loan Party and material in the operation or conduct of such Loan Party's business as currently conducted and proposed to be conducted by such Loan Party, without condition, restriction or payment of any kind (other than license payments in the ordinary course of business) to any third party. To Borrower's knowledge, each Loan Party owns or has the right to use, pursuant to valid licenses, all software development tools, library functions, compilers and all other third-party software and other items that are material to such Loan Party's business and used in the design, development, promotion, sale, license, manufacture, import, export, use or distribution of Borrower Products that are material to such Loan Party's business, in each case, except customary covenants in inbound license agreements and equipment leases where such Loan Party is the licensee or lessee.

(p) To Borrower's knowledge, no material software or other materials used by any Loan Party or any of their Subsidiaries (or used in any Borrower Products) are subject to an open-source or similar license (including but not limited to the General Public License, Lesser General Public License, Mozilla Public License, or Affero License) in a manner that would cause such software or other materials to have to be (i) distributed to third parties at no charge or a minimal charge (royalty-free basis); (ii) licensed to third parties to modify, make derivative works based on, decompile, disassemble, or reverse engineer; or (iii) used in a manner that requires disclosure or distribution in source code form.

5.11 Borrower Products. Except as set forth on Schedule 5.11 or in the Compliance Certificate delivered for the last month of the most recently ended fiscal quarter in accordance with

Section 7.1(d), no Intellectual Property owned by Borrower and material in its business or Borrower Product has been or is subject to any actual or, to the knowledge of Borrower, threatened in writing, litigation, third party proceeding (including any third party proceeding in the United States Patent and Trademark Office or any corresponding foreign office or agency) or outstanding decree, order, judgment, settlement agreement or stipulation that restricts in any manner Borrower's use, transfer or licensing thereof or that could reasonably be expected to adversely affect the validity, use or enforceability thereof. There is no decree, order, judgment, agreement, stipulation, arbitral award or other provision entered into in connection with any litigation or third party proceeding that obligates Borrower to grant licenses or ownership interest in any future Intellectual Property related to the operation or conduct of the business of Borrower or Borrower Products to an extent that could reasonably be expected to materially adversely affect such Loan Party's ability to perform or pay the Secured Obligations in accordance with the Loan Documents. Borrower has not received any written notice or claim, or, to the knowledge of Borrower, oral notice or claim, challenging or questioning Borrower's ownership in any material Intellectual Property (or written notice of any claim challenging or questioning the ownership in any licensed Intellectual Property of the owner thereof) or suggesting that any third party has any claim of legal or beneficial ownership with respect thereto nor, to Borrower's knowledge, is there a reasonable basis for any such claim.

5.12 Financial Accounts. Exhibit D, as may be updated by Borrower in a written notice provided to Agent after the Closing Date, is a true, correct and complete list of (a) all banks and other financial institutions at which Borrower or any Subsidiary maintains Deposit Accounts and (b) all institutions at which Borrower or any Subsidiary maintains an account holding Investment Property, and such exhibit correctly identifies the name, address and telephone number of each bank or other institution, the name in which the account is held, a description of the purpose of the account, and the complete account number therefor. None of the Loan Parties or any of their Subsidiaries owns or holds any Digital Assets.

5.13 Employee Loans. Except for loans constituting Permitted Investments or as described on Schedule 5.13, Borrower has no outstanding loans to any employee, officer or director of Borrower nor has Borrower guaranteed the payment of any loan made to an employee, officer or director of Borrower by a third party.

5.14 Capitalization and Subsidiaries. Borrower does not own any stock, partnership interest or other securities of any Person, except for Permitted Investments. Attached as Schedule 5.14, as may be updated by Borrower in a written notice provided after the Closing Date, is a true, correct and complete list of each Subsidiary.

5.15 Solvency. The fair salable value of Borrower's consolidated assets (including goodwill minus disposition costs) exceeds the fair value of Borrower's liabilities; Borrower is not left with unreasonably small capital after the transactions in this Agreement; and Borrower, and Borrower and each of its Subsidiaries (on a consolidated basis), are able to pay their debts (including trade debts) as they mature. The amount of any contingent liability at any time shall be computed as the amount that would reasonably be expected to become an actual and matured liability.

SECTION 6. INSURANCE; INDEMNIFICATION

6.1 Coverage. Borrower shall cause to be carried and maintained commercial general liability insurance covering Borrower and its Subsidiaries, on an occurrence form, against risks and in such amounts customarily insured against in Borrower's line of business. Such risks shall include the risks of bodily injury, including death, property damage, personal injury, and contractual liability per the terms of the indemnification agreement found in Section 6.3. Borrower must maintain a

minimum of [**] Dollars ($[**]) of commercial general liability insurance for each occurrence. Borrower maintains and shall continue to maintain a minimum of [**] Dollars ($[**]) of directors' and officers' insurance for each occurrence and [**] Dollars ($[**]) in the aggregate. Until the Secured Obligations are Paid in Full, Borrower shall also cause to be carried and maintained insurance upon the business and assets of Borrower and its Subsidiaries, insuring against all risks of physical loss or damage howsoever caused, in an amount not less than the full replacement cost of the Collateral, provided that such insurance may be subject to standard exceptions and deductibles. If Borrower fails to obtain the insurance called for by this Section 6.1 or fails to pay any premium thereon or fails to pay any other amount which Borrower is obligated to pay under this Agreement or any other Loan Document or which may be required to preserve the Collateral, Agent may obtain such insurance or make such payment, and all amounts so paid by Agent are immediately due and payable, bearing interest at the then highest rate applicable to the Secured Obligations, and secured by the Collateral. Agent will make reasonable efforts to provide Borrower with notice of Agent obtaining such insurance at the time it is obtained or within a reasonable time thereafter. No payments by Agent are deemed an agreement to make similar payments in the future or Agent's waiver of any Event of Default.

6.2 Certificates. Borrower shall deliver to Agent certificates of insurance that evidence Borrower's compliance with its insurance obligations in Section 6.1 and the obligations contained in this Section 6.2: (i) on the Closing Date, and (ii) thereafter, on the date of delivery of each Compliance Certificate delivered for the last month of a fiscal quarter policy renewal or modification after the Closing Date that results in newly issued certificates. Borrower's insurance certificate shall reflect Agent (shown as "Hercules Capital, Inc., as Agent, and its successors and/or assigns") is an additional insured for commercial general liability, a lenders loss payable for all risk property damage insurance, subject to the insurer's approval, and a lenders loss payable for property insurance and additional insured for liability insurance for any future insurance that Borrower may acquire from such insurer. Attached to the certificates of insurance will be additional insured endorsements for liability and lender's loss payable endorsements for all risk property damage insurance. All certificates of insurance will provide for a minimum of thirty (30) days advance written notice to Agent of cancellation (other than cancellation for non-payment of premiums, for which ten (10) days' advance written notice shall be sufficient) or any other change adverse to Agent's interests. Any failure of Agent to scrutinize such insurance certificates for compliance is not a waiver of any of Agent's rights, all of which are reserved. At Agent's request, Borrower shall provide Agent with copies of each insurance policy, and upon entering into or amending any insurance policy required hereunder in any material respect, Borrower shall, on or before the date of the delivery of each Compliance Certificate delivered for the last month of a fiscal quarter following such entry or amendment, provide Agent with updated insurance certificates with respect to such policies, and, upon Agent's request, copies of such policies.

6.3 Indemnity. Borrower agrees to indemnify and hold Agent, Lenders and their officers, directors, employees, agents, in-house attorneys, representatives and shareholders (each, an "Indemnified Person") harmless from and against any and all third-party claims, costs, expenses, damages and liabilities (including such claims, costs, expenses, damages and liabilities based on liability in tort, including strict liability in tort), including reasonable and documented out-of-pocket attorneys' fees and out-of-pocket disbursements and other costs of investigation or defense (including those incurred upon any appeal) (collectively, "Liabilities"), that may be instituted or asserted against or incurred by such Indemnified Person as the result of credit having been extended, suspended or terminated under this Agreement and the other Loan Documents or the administration of such credit, or in connection with or arising out of the transactions contemplated hereunder and thereunder, or any actions or failures to act in connection therewith, or arising out of the disposition or utilization of the Collateral, excluding in all cases Liabilities to the extent such Liabilities arise

solely out of gross negligence or willful misconduct of any Indemnified Person or changes in income tax rates. This Section 6.3 shall not apply with respect to Taxes other than any Taxes that represent losses, claims, damages, etc. arising from any non-Tax claim. In no event shall any Indemnified Person be liable on any theory of liability for any special, indirect, consequential or punitive damages (including any loss of profits, business or anticipated savings). This Section 6.3 shall survive the repayment of indebtedness under, and otherwise shall survive the expiration or other termination of, this Agreement, in each case, subject to the applicable statute of limitations.

SECTION 7. COVENANTS OF BORROWER

Borrower agrees as follows:

7.1 Financial Reports. Borrower shall furnish to Agent the financial statements and reports listed hereinafter (the "Financial Statements"):

(a) as soon as practicable (and in any event within thirty (30) days) after the end of each month, unaudited interim and year-to-date financial statements as of the end of such month (prepared on a consolidated), including balance sheet and related statements of income and cash flows, all certified by a duly authorized officer of Borrower to the effect that they have been prepared in accordance with GAAP, except (i) for the absence of footnotes, (ii) that they are subject to normal year-end adjustments, and (iii) they do not contain certain non-cash items that are customarily included in quarterly and annual financial statements;

(b) as soon as practicable (and in any event within forty-five (45) days) after the end of each calendar quarter), unaudited interim and year-to-date financial statements as of the end of such calendar quarter (prepared on a consolidated basis), including balance sheet and related statements of income and cash flows, certified by a duly authorized officer of Borrower to the effect that they have been prepared in accordance with GAAP, except (i) for the absence of footnotes, and (ii) that they are subject to normal year-end adjustments;

(c) as soon as practicable (and in any event within ninety (90) days) after the end of each fiscal year, audited financial statements as of the end of such year (prepared on a consolidated basis), including balance sheet and related statements of income and cash flows, and setting forth in comparative form the corresponding figures for the preceding fiscal year, certified without qualification (other than any going concern qualification) by Deloitte & Touche LLP or another firm of independent certified public accountants selected by Borrower and reasonably acceptable to Agent, accompanied by any management report from such accountants;

(d) as soon as practicable (and in any event within thirty (30) days) after the end of each month, a Compliance Certificate;

(e) as soon as practicable (and in any event within thirty (30) days) after the end of each month, a report showing agings of accounts receivable and accounts payable;

(f) promptly after the sending or filing thereof, as the case may be, copies of any proxy statements, financial statements, information or reports that Company has made available to holders of its common stock and copies of any regular, periodic and special reports or registration statements that Company files with the Securities and Exchange Commission or any Governmental Authority that may be substituted therefor, or any national securities exchange;

(g) upon Agent's request, copies of any material Governmental Approvals obtained by Borrower or any of its Subsidiaries;

(h) promptly upon the request of Agent or Lender at any time after the achievement of Approval Milestone 1 or Approval Milestone 2, the most recently available materials that the Borrower provides to its directors detailing key metrics relating to Borrower's commercial performance;

(i) financial and business projections promptly following their approval by Company's Board of Directors at the end of each fiscal year, and in any event, within sixty (60) days after the end of Borrower's fiscal year, as well as budgets, operating plans and other financial information reasonably requested by Agent;

(j) on the date of delivery of any Compliance Certificate delivered for the last month of a fiscal quarter, insurance renewal statements of insurance policies required to be maintained in accordance with Section 6.1;

(k) prompt notice of any legal process that is reasonably likely to result in damages, expenses or liabilities of Borrower in excess of [**] Dollars ($[**]); and

(l) prompt (but in any event no more than two (2) Business Days') notice if Borrower or any Subsidiary has knowledge that Borrower, or any Subsidiary or Affiliate of Borrower, is listed on the OFAC Lists or (a) is convicted on, (b) pleads *nolo contendere* to, (c) is indicted on, or (d) is arraigned and held over on charges involving money laundering or predicate crimes to money laundering.

Borrower shall not (without the consent of Agent, such consent not to be unreasonably withheld or delayed), make any change in its (a) accounting policies or reporting practices, except as required by GAAP or pursuant to applicable securities laws or regulations of the SEC or (b) fiscal years or fiscal quarters. The fiscal year of Borrower shall end on December 31.

The executed Compliance Certificate, and all Financial Statements required to be delivered hereunder shall be sent per instructions (i) specified on Addendum 2 or (ii) otherwise provided by Agent to Borrower via a written notice from time to time.

Notwithstanding the foregoing, documents required to be delivered under Sections 7.1(a), (b), (c), (f) or (k) (to the extent any such documents are included in materials otherwise filed with the SEC) may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date on which Borrower makes such documented publicly available.

7.2 Management Rights. Borrower shall permit any representative that Agent or Lenders authorizes, including its attorneys and accountants, to inspect the Collateral and examine and make copies and abstracts of the books of account and records of Borrower at reasonable times and upon reasonable notice during normal business hours; provided, however, that so long as no Event of Default has occurred and is continuing, such examinations shall be limited to no more often than once per fiscal year. In addition, in connection with such inspections, any such representative shall have the right to meet with management and officers of Borrower to discuss such books of account and records at such time. In addition, Agent or Lenders shall be entitled at reasonable times and intervals to consult with and advise the management and officers of Borrower concerning significant business issues affecting Borrower. Such consultations shall not unreasonably interfere with Borrower's business operations. The parties intend that the rights granted Agent and Lenders

shall constitute "management rights" within the meaning of 29 C.F.R. Section 2510.3-101(d)(3)(ii), but that any advice, recommendations or participation by Agent or Lenders with respect to any business issues shall not be deemed to give Agent or Lenders, nor be deemed an exercise by Agent or Lenders of, control over Borrower's management or policies.

7.3 Further Assurances. Borrower shall, and shall cause each other Loan Party to, from time to time execute, deliver and file, alone or with Agent, any financing statements, security agreements, collateral assignments, notices, control agreements, promissory notes or other documents to perfect, give the highest priority to Agent's Lien on the Collateral or otherwise evidence Agent's rights herein. Borrower shall from time to time procure any instruments or documents as may be reasonably requested by Agent, and take all further action that may be necessary, or that Agent may reasonably request, to perfect and protect the Liens granted hereby or pursuant to applicable Loan Documents. In addition, and for such purposes only, Borrower hereby authorizes Agent to execute and deliver on behalf of Borrower and to file such financing statements (including an indication that the financing statement covers "all assets or all personal property" of Borrower in accordance with Section 9-504 of the UCC), and Borrower hereby authorizes Agent, at any time during the existence of an Event of Default, to execute and deliver on behalf of Borrower any collateral assignments, notices, control agreements, security agreements and other documents without the signature of Borrower either in Agent's name or in the name of Agent as agent and attorney-in-fact for Borrower. Borrower shall, in good faith and in its reasonable commercial discretion, in each case, subject to the terms of this Agreement, protect and defend Borrower's title to the Collateral and Agent's Lien thereon against all Persons claiming any interest adverse to Borrower or Agent other than Permitted Liens.

7.4 Indebtedness. Borrower shall not create, incur, assume, guarantee or be or remain liable with respect to any Indebtedness, or permit any Subsidiary to do so, other than Permitted Indebtedness, or prepay any Indebtedness or take any actions which impose on Borrower an obligation to prepay any Indebtedness, except for (a) the conversion of Indebtedness into equity securities and the payment of cash in lieu of fractional shares in connection with such conversion, (b) purchase money Indebtedness or Indebtedness in respect of capital leases permitted hereunder pursuant to its then applicable payment schedule, (c) prepayment by any Subsidiary of (i) inter-company Indebtedness owed by such Subsidiary to any Borrower, or (ii) if such Subsidiary is not a Borrower, intercompany Indebtedness owed by such Subsidiary to another Subsidiary that is not a Borrower, (d) payments made on Subordinated Indebtedness to the extent permitted under the relevant Subordination Agreement, (e) the issuance of and performance of obligations under Permitted Convertible Debt, (f) the conversion, exchange, exercise, repurchase, redemption of Permitted Convertible Debt, or the exercise or early unwind or termination of Permitted Bond Hedge Transactions and Permitted Warrant Transactions, in each case so long as any cash prepayments made by Borrower in connection therewith are Permitted Convertible Debt Financing Payments, (g) Indebtedness owed under corporate credit cards constituting Permitted Indebtedness and prepaid in the ordinary course of business, (h) Permitted Indebtedness with the proceeds of Permitted Indebtedness, (i) prepayment of Indebtedness permitted under clauses (i), (iv), (vii), and (xix) of the definition of Permitted Indebtedness, or (j) as otherwise permitted hereunder or approved in writing by Agent. Notwithstanding the foregoing, payments constituting Thermo Fisher Installment Payments made in compliance with Section 7.25 shall be permitted.

7.5 Collateral. Borrower shall at all times (a) keep the Collateral and all other property and assets used in Borrower's business or in which Borrower now or hereafter holds any interest free and clear from any Liens whatsoever (except for Permitted Liens), and (b) shall give Agent prompt written notice of any Liens thereon (other than Permitted Liens). Borrower shall not agree with any Person other than Agent or Lenders not to encumber its property other than in connection

with Permitted Liens. Borrower shall not enter into or suffer to exist or become effective any agreement that prohibits or limits the ability of any Borrower to create, incur, assume or suffer to exist any Lien upon any of its property (including Intellectual Property), whether now owned or hereafter acquired, to secure its obligations under the Loan Documents to which it is a party other than (i) this Agreement and the other Loan Documents, (ii) any agreements governing any purchase money Liens or capital lease obligations otherwise permitted hereby (in which case, any prohibition or limitation shall only be effective against the assets financed thereby), (iii) agreements governing cash collateral arrangements constituting Permitted Liens restricting Liens on cash collateral accounts and the Cash therein, (iv) restrictions on the assignment of the Extended Payment Schedule, under and as defined in the Thermo Fisher Agreement and (v) customary restrictions on the assignment of leases, licenses and other agreements. Borrower shall cause its Subsidiaries to protect and defend such Subsidiary's title to its assets from and against all Persons claiming any interest adverse to such Subsidiary (other than Permitted Liens), and Borrower shall cause its Subsidiaries at all times to keep such Subsidiary's property and assets free and clear from any legal process or Liens whatsoever (except for Permitted Liens).

7.6 Investments. Borrower shall not directly or indirectly acquire or own, or make any Investment in or to any Person, or permit any of its Subsidiaries to do so, other than Permitted Investments. No Loan Party shall directly or indirectly acquire or own, nor make any Investment in Digital Assets, nor permit any of its Subsidiaries so to do. Notwithstanding the foregoing, and for the avoidance of doubt, this Section 7.6 shall not prohibit Permitted Convertible Debt Financing Payments.

7.7 Distributions. Borrower shall not, and shall not allow any Subsidiary to, (a) repurchase or redeem any class of stock or other Equity Interest other than pursuant to employee, director or consultant repurchase plans or other similar agreements, provided, however, in each case the repurchase or redemption price does not exceed the fair market value for such stock or Equity Interest unless required by the terms of such agreement or plan, or pursuant to a public repurchase of securities in compliance with the requirements of SEC Rule 10b-18, or (b) declare or pay any cash dividend or make any other cash distribution on any class of stock or other Equity Interest, except that a Subsidiary may pay dividends or make other distributions to Borrower or any Subsidiary of Borrower, or (c) except for Permitted Investments, lend money to any employees, officers or directors or guarantee the payment of any such loans granted by a third party in excess of [**] Dollars ($[**]) in the aggregate, or (d) convert any of its convertible securities into other securities pursuant to the terms of such convertible securities or otherwise in exchange thereof other than pursuant to the terms thereof so long as such conversion does not result in a Change of Control, or (e) waive, release or forgive any Indebtedness owed by any employees, officers or directors in excess of [**] Dollars ($[**]) in the aggregate other than cancellation of Indebtedness in connection with the repurchase of Equity Interests permitted under clause (a) above or clause (iii) of the definition of Permitted Investments. Notwithstanding the foregoing, payments constituting Thermo Fisher Installment Payments made in compliance with Section 7.25 shall be permitted.

Notwithstanding the foregoing, and for the avoidance of doubt, this Section 7.7 shall not prohibit Permitted Convertible Debt Financing in accordance with the terms of the Payments.

7.8 Transfers. Except for Permitted Transfers, Borrower shall not, and shall not permit any Subsidiary to, voluntarily or involuntarily transfer, sell, lease, license, lend or in any other manner convey ("Transfer") any equitable, beneficial or legal interest in any material portion of its assets (including, without limitation, pursuant to a Division); provided that licenses of Company IP (to the extent not constituting Permitted Transfers) may be made with the consent of the Required Lenders (such consent not to be unreasonably withheld or delayed). Notwithstanding the foregoing,

and for the avoidance of doubt, this Section 7.8 shall not prohibit the conversion by holders of any Permitted Convertible Debt Financing in accordance with the terms of the indenture governing such Permitted Convertible Debt Financing or Borrower's delivery of the conversion consideration in connection therewith; provided that the conversion consideration (or exchange or inducement consideration) paid to such holders constitutes a Permitted Convertible Debt Financing Payment.

7.9 Mergers and Consolidations. Except for Permitted Acquisitions, Borrower shall not, nor will it permit any Subsidiary to, merge, dissolve, liquidate, consolidate with or into another Person, or dispose of (whether in one transaction or in a series of transactions) all or substantially all of its assets (whether now owned or hereafter acquired) to or in favor of any Person (other than mergers or consolidations of (a) a Subsidiary which is not a Borrower into another Subsidiary or into Borrower or (b) a Borrower into another Borrower).

7.10 Taxes. Borrower shall, and shall cause each of its Subsidiaries to, pay when due all material Taxes of any nature whatsoever now or hereafter imposed or assessed against Borrower or such Subsidiary or the Collateral or upon Borrower's (or such Subsidiary's) ownership, possession, use, operation or disposition thereof or upon Borrower's (or such Subsidiary's) rents, receipts or earnings arising therefrom. Borrower shall, and shall cause each of its Subsidiaries to, accurately file on or before the due date therefor (taking into account proper extensions) all federal and state income Tax returns and other material Tax returns required to be filed. Notwithstanding the foregoing, Borrower and its Subsidiaries may contest, in good faith and by appropriate proceedings diligently conducted, Taxes for which Borrower and its Subsidiaries maintain adequate reserves in accordance with GAAP.

7.11 Corporate Changes.

(a) Neither Borrower nor any Subsidiary shall change its corporate name, legal form or jurisdiction of formation without twenty (20) days' prior written notice to Agent.

(b) Neither Borrower nor any Subsidiary shall suffer a Change in Control.

(c) Neither Borrower nor any Subsidiary shall relocate its chief executive office or its principal place of business unless: (i) it has provided prior written notice to Agent; and (ii) such relocation shall be within the continental United States of America.

(d) If Borrower intends to add any new offices or business locations, including warehouses, containing any portion of Borrower's assets or property valued, individually or in the aggregate, in excess of [**] Dollars ($[**]) (other than offices, business locations or warehouses holding primarily (i) works-in-progress, raw materials or otherwise in the supply chain for commercial manufacturing or sale of Borrower Products, (ii) inventory or other goods in transit, or (iii) assets (other than equipment) in connection with clinical and pre-clinical studies, including contract manufacturing organizations, distribution service firms, contract research organizations, clinical sites, clinical investigators and other institutions), then Borrower will use commercially reasonable efforts to cause the landlord of any such new offices or business locations, including warehouses, to execute and deliver a landlord consent in form and substance satisfactory to Agent within thirty (30) days.

(e) If Borrower intends to deliver any portion of Borrower's assets or property valued, individually or in the aggregate, in excess of [**] Dollars ($[**]) to a bailee (other than bailees or other third parties in possession of (i) works-in-progress, raw materials or otherwise in the supply chain for commercial manufacturing or sale of Borrower Products, (ii) inventory or other goods in

transit, or (iii) assets (other than equipment) in connection with clinical and pre-clinical studies, including contract manufacturing organizations, distribution service firms, contract research organizations, clinical sites, clinical investigators and other institutions), and Agent and such bailee are not already parties to a bailee agreement governing both the Collateral and the location to which Borrower intends to deliver the Collateral, then Borrower will use commercially reasonable efforts to cause such bailee to execute and deliver a bailee agreement in form and substance satisfactory to Agent within thirty (30) days.

(f) The Borrower will not, and will not permit any Subsidiary to, engage to any material extent in any business other than those businesses conducted by the Borrower and its Subsidiaries on the date hereof or any business reasonably related or incidental thereto or representing a reasonable expansion thereof.

(g) Without the prior written consent of Agent, the Borrower will not make, or agree to make, any modification, amendment or waiver of any of the terms or provisions of Borrower's Organizational Documents that is adverse to Agent or any of the Lenders.

7.12 Deposit Accounts. No Loan Party shall maintain any Deposit Accounts, any accounts or sub-accounts in connection with an insured cash sweep program, or accounts holding Investment Property, except with respect to which Agent has an Account Control Agreement on terms and conditions satisfactory to Agent in its sole discretion, provided that no Account Control Agreement shall be required for (i) any Excluded Account or (ii) any other deposit accounts, so long as the aggregate amount in all such deposit accounts do not exceed [**] Dollars ($[**]) on any day. None of the Loan Parties or any of their Subsidiaries shall own or hold any Digital Assets.

7.13 Joinder of Subsidiaries. Borrower shall notify Agent of each Subsidiary formed or acquired subsequent to the Closing Date (including any new Subsidiary formed by Division) and, within thirty (30) days of such formation or acquisition (or such longer period of time as agreed to by Agent in writing in its sole discretion), shall cause any such Subsidiary (other than an Excluded Subsidiary) to execute and deliver to Agent a Joinder Agreement and such other documents and instruments as shall be requested by Agent to effectuate the transactions contemplated by such Joinder Agreement (in each case in form and substance acceptable to Agent), or, if requested by Agent, a Guaranty and appropriate collateral security documents to secure the obligations pursuant to such Guaranty (in each case in form and substance acceptable to Agent); it being agreed that if such new Subsidiary is formed by a Division, the foregoing requirements shall be satisfied substantially concurrently with the formation of such Subsidiary. In the event one or more Subsidiaries that were previously Excluded Subsidiaries no longer qualify as an Excluded Subsidiary, such Subsidiaries shall be subject to the requirements of the immediately preceding sentence.

7.14 Regulatory and Product Notices. The Borrower, on behalf of the Loan Parties, shall promptly (but in any event within ten (10) Business Days) after the receipt or occurrence thereof notify Agent of:

(a) any written notice that the FDA (or international equivalent) is limiting, suspending or revoking any Registration (including, but not limited to, by the issuance of a clinical hold),

(b) any written notice from a Governmental Authority that a Loan Party or its Subsidiaries has become subject to any regulatory action,

(c) any written notice from the FDA indicating the exclusion or debarment from any governmental healthcare program or debarment or disqualification by FDA (or international equivalent) of any Loan Party or its Subsidiaries,

(d) any written notice from a Governmental Authority that a Loan Party or any Subsidiary, or any of their licensees or sublicensees (including licensees or sublicensees under any Material Agreement), is being investigated or is the subject of any allegation of potential or actual violations of any FDA Laws,

(e) any written notice from a Governmental Authority that any Borrower Product has been seized, withdrawn, recalled, detained, or subject to a suspension of manufacturing, or the commencement of any proceedings in the United States or any other jurisdiction seeking the withdrawal, recall, suspension, import detention, or seizure of any Borrower Product are pending or threatened in writing against Borrower or its Subsidiaries, or

(f) any written notice from the FDA narrowing or otherwise limiting the scope of marketing authorization or the labeling of the products of any Loan Party and its Subsidiaries under any Registration;

except, in each case of (a) through (f) above, where such action would not reasonably be expected to have, either individually or in the aggregate, any Material Regulatory Liabilities.

7.15 Notification of Event of Default. Borrower shall notify Agent promptly (but in any event within two (2) Business Days after the occurrence) of the occurrence of any Event of Default.

7.16 SBA. One or more affiliates of Agent have received a license from the U.S. Small Business Administration ("SBA") to extend loans as a small business investment company ("SBIC") pursuant to the Small Business Investment Act of 1958, as amended, and the associated regulations, as amended (collectively, the "SBIC Act"). Portions of the Loan to Borrower may be made by a Lender that is a SBIC. Addendum 3 to this Agreement outlines various responsibilities of Agent, each Lender and Borrower associated with a loan made by a SBIC, and such Addendum 3 is hereby incorporated in this Agreement. Borrower shall immediately notify Agent of any failure to comply with its obligations under Addendum 3 upon acquiring knowledge thereof.

7.17 Use of Proceeds. Borrower agrees that the proceeds of the Loans shall be used solely to pay related fees and expenses in connection with this Agreement and for working capital and general corporate purposes. The proceeds of the Loans will not be used in violation of Anti-Corruption Laws or applicable Sanctions.

7.18 MSC Investment Conditions. At any time that the MSC Subsidiary has any assets or liabilities, Borrower shall satisfy the MSC Investment Conditions at all times.

7.19 Material Agreement. Borrower shall give prompt (and in any event within ten (10) Business Days) written notice to Agent of entering into a Material Agreement or materially amending or terminating a Material Agreement; provided that to the extent disclosure of any such Material Agreement, material amendment or termination is included in materials otherwise filed with the SEC, such notice shall be deemed to have been delivered on the date on which Borrower makes such disclosure publicly available.

7.20 Compliance with Laws.

(a) Borrower (i) shall maintain, and shall cause its Subsidiaries to maintain, compliance in all material respects with all applicable laws, rules or regulations (including any law, rule or regulation with respect to the making or brokering of loans or financial accommodations), and (ii) shall, or cause its Subsidiaries to, obtain and maintain all required governmental authorizations, approvals, licenses, franchises, permits or registrations reasonably necessary in connection with the conduct of Borrower's business. Borrower shall not become an "investment company," a company that would be an "investment company" except for the exclusion from the definition of "investment company" in Section 3(c) of the 1940 Act, or a company controlled by an "investment company" under the 1940 Act, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation X, T and U of the Federal Reserve Board of Governors).

(b) Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries permit any controlled Affiliate to, directly or indirectly, knowingly enter into any documents, instruments, agreements or contracts with any Person listed on the OFAC Lists. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries, permit any controlled Affiliate to, directly or indirectly, (i) conduct any business or engage in any transaction or dealing with any Blocked Person, including, without limitation, the making or receiving of any contribution of funds, goods or services to or for the benefit of any Blocked Person, (ii) deal in, or otherwise engage in any transaction relating to, any property or interests in property blocked pursuant to Executive Order No. 13224 or any similar executive order or other Anti-Terrorism Law, or (iii) engage in or conspire to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in Executive Order No. 13224 or other Anti-Terrorism Law.

(c) Borrower has implemented and shall maintain in effect policies and procedures designed to ensure compliance by Borrower, its Subsidiaries and their respective directors, officers, employees and agents with Anti-Corruption Laws and applicable Sanctions, and Borrower, its Subsidiaries and their respective officers and employees and to the knowledge of Borrower its directors and agents, are in compliance with Anti-Corruption Laws and applicable Sanctions in all material respects.

(d) None of Borrower, any of its Subsidiaries or any of their respective directors, officers or employees, or to the knowledge of Borrower, any agent for Borrower or its Subsidiaries that will act in any capacity in connection with or benefit from the credit facility established hereby, is a Sanctioned Person. No Loan, use of proceeds or other transaction contemplated by this Agreement will violate Anti-Corruption Laws or applicable Sanctions.

7.21 Financial Covenant.

(a) Minimum Cash. Beginning on the Initial Minimum Cash Test Date and at all times thereafter, Borrower shall maintain Qualified Cash in an amount greater than or equal to the outstanding principal amount of the Secured Obligations, multiplied by (i) prior to Borrower's achievement of either the Approval Milestone I or the Approval Milestone II, sixty percent (60%), and (ii) from and after Borrower's achievement of either the Approval Milestone I or the Approval Milestone II (the "Initial Cash Stepdown"), [**] percent ([**]%) (as applicable, the "Minimum Cash Coverage Percentage"); provided, that, upon Borrower's achievement of the Initial Cash Stepdown and the Commercial Milestone, the Minimum Cash Coverage Percentage shall be reduced to [**] percent ([**]%); provided further that, if Borrower has not achieved either Data Milestone I or Data Milestone II on or before [**], then beginning on [**] the Minimum Cash Coverage Percentage shall be increased to [**] percent ([**]%) until such time as Borrower

achieves either Approval Milestone I or the Approval Milestone II, at which time it shall be decreased to [**] percent ([**]%) and further decreased to [**] percent ([**]%) upon Borrower's achievement of the Initial Cash Stepdown and the Commercial Milestone. Notwithstanding the foregoing, this Section 7.21(a) shall not be required to be complied with at any time in which Company's Market Capitalization for such day is greater than One Billion Six Hundred Fifty Million Dollars ($1,650,000,000).

If any Loan Party makes a cash payment in respect of Permitted Convertible Debt utilizing the Redemption Conditions, Borrower shall, at all times thereafter, maintain Qualified Cash in an amount equal to no less than [**] percent ([**]%) of the Secured Obligations (inclusive of any Prepayment Charge and End of Term Charge that would be due and owing if the outstanding Term Loan Advances were prepaid at the time of measurement).

(b) Minimum Revenue. Beginning on the Initial Minimum Revenue Test Date and tested monthly thereafter, Borrower shall generate Net Product Revenue, measured on a trailing six (6) month basis, of at least [**] percent ([**]%) of the Net Product Revenue included in the Board Approved Forecast for the trailing six (6) month period ending on the last day of such month. Notwithstanding the foregoing, this Section 7.21(b) shall not be required to be complied with for any particular month to the extent that for each day during such month, either (i) Borrower maintains Qualified Cash in an amount greater than or equal to the outstanding principal amount of the Secured Obligations, or (ii) (x) Company's Market Capitalization for such day is greater than One Billion Six Hundred Fifty Million Dollars ($1,650,000,000), and (y) Borrower maintains Qualified Cash in an amount greater than or equal to the outstanding principal amount of the Secured Obligations, multiplied by fifty percent (50%).

7.22 Intellectual Property. Each Borrower shall (i) use commercially reasonable efforts protect, defend and maintain the validity and enforceability of Current Company IP, except in connection with transactions permitted by clause (ix) of Permitted Transfers and (ii) not allow any Intellectual Property material to Borrowers' business to be abandoned (other than in the normal course of prosecution whereby, for example, an application is abandoned in favor of a continuation or divisional application), forfeited or dedicated to the public without Agent's written consent, except in connection with transactions permitted by clause (ix) of Permitted Transfers. If a Borrower (a) obtains any Patent, registered Trademark, registered Copyright, registered mask work, or any pending application for any of the foregoing, whether as owner, licensee or otherwise, or (b) applies for any Patent or the registration of any Trademark, then such Borrower shall concurrently with the delivery of each Compliance Certificate delivered for the last month of a fiscal quarter, provide written notice thereof to Agent and shall execute such intellectual property security agreements (unless such application for Patent is a continuing or divisional application of preexisting Current Company IP) and other documents and take such other actions as Agent may request in its good faith business judgment to perfect and maintain a first priority perfected security interest in favor of Agent in such property; *provided* that, for the avoidance of doubt, (a) and (b) shall not require Borrower to record intellectual security agreements with government offices, such as the USPTO, for Patents and Trademarks but rather Agent's responsibility to record after Borrower execution (if any). If a Borrower decides to register any Copyrights or mask works in the United States Copyright Office, such Borrower shall: (x) provide Agent written notice concurrently with the delivery of each Compliance Certificate delivered for the last month of a fiscal quarter of such Borrower's intent to register such Copyrights or mask works together with a copy of the application it intends to file with the United States Copyright Office (excluding exhibits thereto) and (y) execute an intellectual property security agreement and such other documents and take such other actions as Agent may request in its good faith business judgment to perfect and maintain a first priority perfected security interest in favor of Agent in the Copyrights or mask works intended to be registered with the United

States Copyright Office; and (z) record such intellectual property security agreement with the United States Copyright Office contemporaneously with filing the Copyright or mask work application(s) with the United States Copyright Office.

7.23 Transactions with Affiliates. Except as otherwise described on Schedule 7.23, Borrower shall not, and shall not permit any Subsidiary to, directly or indirectly, enter into or permit to exist any transaction of any kind with any Affiliate of Borrower or such Subsidiary, other than transactions (a) among Loan Parties, (b) on terms that are less favorable to Borrower or such Subsidiary, as the case may be, than those that might be obtained in an arm's length transaction from a Person who is not an Affiliate of Borrower or such Subsidiary, (c) to the extent approved by Borrower's board of directors or a duly authorized committee thereof or a duly authorized officer of Borrower, the payment of reasonable fees to directors of Borrower who are not employees of Borrower or any Subsidiary, and compensation and employee benefit arrangements paid to, and indemnities provided for the benefit of, and severance, separation and consulting agreements or arrangements entered into with, directors, officers or employees of Borrower or its Subsidiaries in the ordinary course of business, (d) the sale and issuance of Borrower's Qualified Equity Interests to Affiliates in a transaction not resulting in a Change in Control, and (e) intercompany transactions expressly permitted by Section 7.

7.24 Permitted Convertible Debt Financing Payments.

(a) Make or permit any payment on Permitted Convertible Debt Financing except (i) interest payments in accordance with the terms of the indenture governing such Permitted Convertible Debt Financing, (ii) Borrower's delivery of conversion consideration in connection with the conversion by holders of any Permitted Convertible Debt Financing in accordance with the terms of the indenture governing such Permitted Convertible Debt Financing or the delivery of Common Stock and Cash in lieu of fractional shares of Common Stock to induce the conversion of Permitted Convertible Debt Financing; provided that the conversion consideration (or inducement consideration) paid to such holders is limited to (A) Common Stock and (B) Cash in lieu of fractional shares of Common Stock, (iii) payments in connection with redemptions or repurchases permitted by Section 7.24(b), or (iv) any other payments if, before and after giving effect to such payments, the Redemption Conditions are satisfied.

(b) Redeem, repurchase or exchange any Permitted Convertible Debt Financing, except (i) the redemption or repurchase of Permitted Convertible Debt Financing in exchange for Common Stock and Cash in lieu of fractional shares of Common Stock; provided that the repurchase consideration paid to the holders of Permitted Convertible Debt Financing is limited to (A) Common Stock, (B) Cash in lieu of fractional shares of Common Stock, (ii) redemptions or repurchases with Cash if, before and after giving effect to such payments, the Redemption Conditions are satisfied, (iii) exchanges for a different series of Permitted Convertible Debt Financing, (iv) redemptions or repurchases with Cash in an amount that does not exceed the proceeds received by Borrower from the substantially concurrent issuance of Common Stock and/or Permitted Convertible Debt Financing (or a permitted refinancing thereof) plus the net cash proceeds, if any, received by Borrower pursuant to the related exercise or early unwind or termination of the related Permitted Bond Hedge Transactions and Permitted Warrant Transactions, if any, pursuant to the immediately following proviso); provided that, substantially concurrently with, or a commercially reasonable period of time before or after, the related settlement date for the convertible notes issued in a Permitted Convertible Debt Financing that is so repurchased, exchanged or converted, Borrower shall exercise or unwind or terminate early (whether in cash, shares or any combination thereof) the portion of the Permitted Bond Hedge Transactions and

Permitted Warrant Transactions, if any, corresponding to such Permitted Convertible Debt Financing that are so repurchased, exchanged or converted.

(c) In no event shall the foregoing permit Borrower to pay holders of Permitted Convertible Debt Financing any Cash (other than cash in lieu of fractional shares) in connection with mandatory repurchase rights granted to such holders upon the occurrence of a "change of control", "fundamental change", "make-whole fundamental change" or any comparable term, unless, before and after giving effect to such payments, the Redemption Conditions are satisfied.

(d) Notwithstanding anything to the contrary set forth in this Section 7.24, and for the avoidance of doubt: (i) Borrower may make any required payment of premium to a counterparty thereunder due in connection with entering into any Permitted Bond Hedge Transaction; (ii) Borrower may make any payment in connection with any Permitted Warrant Transaction by (1) delivery of shares of Borrower's Common Stock (together with cash in lieu of fractional shares) upon net share settlement thereof, (2) set-off, netting and/or payment of an early termination payment or other payment thereunder, in each case, in Borrower's Common Stock and (3) solely to the extent Borrower does not have the option of satisfying such payment obligations through the delivery of shares of Borrower's Common Stock or is otherwise required to satisfy such payment obligations in Cash, set-off, netting and/or payment of an early termination payment or other payment thereunder, in each case, in cash (it being understood and agreed that any payment made in Cash in connection with Permitted Warrant Transactions by set-off, netting and/or payment of an early termination payment or similar payment thereunder, in each case, after using commercially reasonable efforts to satisfy such obligation (or the portion thereof remaining after giving effect to any netting or set-off against termination or similar payments under an applicable Permitted Bond Hedge Transaction) by delivery of shares of Borrower's Common Stock shall be deemed to be a payment obligation required to be satisfied in Cash); and (iii) Borrower may acquire shares or other Equity Interests or cash or a combination thereof under the terms of any Permitted Bond Hedge Transaction or Permitted Warrant Transaction.

Each of the payments permitted by the foregoing Section 7.24(a) – (d) shall be referred to herein as "Permitted Convertible Debt Financing Payments").

7.25 Thermo Fisher Installment Payments. Notwithstanding anything to the contrary in this Agreement, Borrower may make the Thermo Fisher Installment Payments pursuant to any Thermo Fisher Agreement so long as (a) no Default or Event of Default has occurred and is continuing and (b) to the extent the Thermo Fisher Installment Payments constitute Indebtedness, such amounts are unsecured.

SECTION 8. RIGHT TO INVEST

8.1 Borrower shall provide (or in the case of a Subsequent Financing that is a registered offering, Borrower shall use its commercially reasonable efforts to request the managing underwriter(s) of such Subsequent Financing to provide) the Lenders or their permitted assignees or nominees, designated as such in writing to Borrower, the opportunity, in their discretion, to participate in any Subsequent Financing in an aggregate amount of up to the Five Million Dollars ($5,000,000) on the same terms, conditions and pricing afforded to others participating in any such Subsequent Financing, subject to compliance with all applicable securities laws and regulations. For the avoidance of doubt, in the event of a registered offering, to the extent Borrower has used its commercially reasonable efforts as set forth above and the managing underwriter(s) of a Subsequent Financing refuse to allocate securities to Lenders in accordance with the aforementioned request ("Underwriter Refusal"), Borrower shall have no further obligations or liability under this Section

8.1 with respect to such Subsequent Financing. If the Lenders (or their permitted assignees or nominees) elect to participate in any Subsequent Financing, the Lenders (or their permitted assignees or nominees, as applicable) participating in such Subsequent Financing agree to become a party to the agreements executed by the other investors participating in such Subsequent Financing, including with respect to obligations of confidentiality or as may otherwise be required by the Securities Act of 1933, as amended (the "Act"), and the rules and regulations promulgated by the Securities and Exchange Commission thereunder. Borrower, or an investment bank or underwriter engaged on Borrower's behalf, shall provide the Lenders or their permitted assignees or nominees at least one (1) Business Day's notice of any planned Subsequent Financing. This Section 8.1, and all rights and obligations provided for hereunder, shall terminate upon the earliest to occur of (a) termination of this Agreement, (b) such time that the Lenders or their assignees or nominees, have purchased Borrower's Equity Interests in an aggregate amount of at least Five Million Dollars ($5,000,000) in one or more Subsequent Financings and (c) Borrower extending (or causing to be extended) two (2) such offers to permit the Lenders or their permitted assignees or nominees the opportunity to participate in Subsequent Financings; provided that any Subsequent Financing resulting in an Underwriter Refusal shall not be included for purposes of achieving two (2) such offers.

SECTION 9. EVENTS OF DEFAULT

The occurrence of any one or more of the following events shall be an "Event of Default":

9.1 Payments. A Loan Party fails to pay any amount due under this Agreement or any of the other Loan Documents on the due date; provided, however, that an Event of Default shall not occur on account of a failure to pay due solely to an administrative or operational error of Agent or Lenders or Borrower's bank if Borrower had the funds to make the payment when due and makes the payment within three (3) Business Days following Borrower's knowledge of such failure to pay; or

9.2 Covenants. A Loan Party breaches or defaults in the performance of any covenant or Secured Obligation under this Agreement, or any of the other Loan Documents or any other agreement among Borrower, Agent and Lenders, and (a) with respect to a Default under any covenant under this Agreement (other than under Sections 4.5, 6, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9, 7.15, 7.17, 7.18, 7.19, 7.21, 7.22, 7.24 and 7.25), any other Loan Document, or any other agreement among Borrower, Agent and Lenders, such default continues for more than twenty (20) days after the earlier of the date on which (i) Agent or Lenders has given notice of such default to Borrower and (ii) Borrower has actual knowledge of such default or (b) with respect to a Default under any of Sections 4.5, 6, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9, 7.15, 7.17, 7.18, 7.19, 7.21, 7.22 7.24 and 7.25), the occurrence of such Default; or

9.3 Material Adverse Effect. A circumstance has occurred that could reasonably be expected to have a Material Adverse Effect; provided that the occurrence of the following, individually, shall not, in and of itself, constitute a "Material Adverse Effect" hereunder: (i) the failure to achieve any Milestone, (ii) adverse results or delays with respect to, or the failure to achieve, any clinical or non-clinical trial goals or objectives, (iii) the denial, delay or limitation or qualification of approval of the FDA or other regulatory agency with respect to any proposed drug or other Borrower Products, or (iv) any revisions to or termination of a strategic alliance, joint venture, co-promotion, co-commercialization or co-development agreements or license arrangement maintained by Borrower so long as the same does not affect the ability of Borrower to perform or pay the Secured Obligations in accordance with the terms of the Loan Documents; or

9.4 Representations. Any representation or warranty made by any Loan Party in any Loan Document shall have been false or misleading in any material respect when made or when deemed made; or

9.5 Insolvency. (a) A Loan Party or any of its Subsidiaries fails to be solvent as described under Section 5.15 hereof; (b) a Loan Party or any of its Subsidiaries begins an Insolvency Proceeding; or (c) an Insolvency Proceeding is begun against a Loan Party or any of its Subsidiaries and is not dismissed or stayed within forty-five (45) days (but no Advances shall be made while any of the conditions described in clause (a) exist or until any Insolvency Proceeding is dismissed); or

9.6 Judgments; Penalties. One or more fines, penalties or final judgments, orders or decrees for the payment of money in an amount, individually or in the aggregate, of at least [**] Dollars ($[**]) (not covered by independent third-party insurance as to which liability has been accepted by such insurance carrier) shall be rendered against any Loan Party or any of its Subsidiaries by any Governmental Authority, and the same are not, within twenty (20) days after the entry, assessment or issuance thereof, discharged, or after execution thereof, or stayed pending appeal, or such judgments are not discharged prior to the expiration of any such stay (provided that no Advances shall be made prior to the discharge, or stay of such fine, penalty, judgment, order or decree); or

9.7 Attachment; Levy; Restraint on Business.

(a) (i) The service of process seeking to attach, by trustee or similar process, any funds of any Loan Party or any of its Subsidiaries, or (ii) a notice of lien or levy is filed against any of any Loan Party's or any of its Subsidiaries' assets by any Governmental Authority, and the same under subclauses (i) and (ii) hereof are not, within twenty (20) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); provided, however, no Advances shall be made during any twenty (20) day cure period; or

(b) (i) any material portion of any Loan Party's or any of its Subsidiaries' assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents any Loan Party from conducting all or any material part of its business

9.8 Other Obligations. The occurrence of any default in which the Loan Party is the defaulting party under (i) any agreement or obligation of a Loan Party involving any Indebtedness in excess of [**] Dollars ($[**]), or (ii) any Material Agreement to the extent such default results in a right by a third party or parties, whether or not exercised, to terminate such Material Agreement or accelerate payments in excess of [**] Dollars ($[**]) owed thereunder.

SECTION 10. REMEDIES

10.1 General. Upon the occurrence and during the continuation of any one or more Events of Default, Agent may, and at the direction of the Required Lenders shall, accelerate and demand payment of all or any part of the outstanding Secured Obligations together with a Prepayment Charge and declare them to be immediately due and payable (provided, that upon the occurrence of an Event of Default of the type described in Section 9.5, all of the Secured Obligations (including, without limitation, the Prepayment Charge and the End of Term Charge) shall automatically be accelerated and made due and payable, in each case without any further notice or act). Borrower hereby irrevocably appoints Agent as its lawful attorney-in-fact to: (a) exercisable following the occurrence and during the continuance of an Event of Default, (i) sign Borrower's name on any invoice or bill of lading for any account or drafts against account debtors; (ii) demand,

collect, sue, and give releases to any account debtor for monies due, settle and adjust disputes and claims about the accounts directly with account debtors, and compromise, prosecute, or defend any action, claim, case, or proceeding about any Collateral (including filing a claim or voting a claim in any bankruptcy case in Agent's or Borrower's name, as Agent may elect); (iii) make, settle, and adjust all claims under Borrower's insurance policies; (iv) pay, contest or settle any Lien, charge, encumbrance, security interest, or other claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; (v) transfer the Collateral into the name of Agent or a third party as the UCC permits; (vi) receive, open and dispose of mail addressed to Borrower; (vii) endorse Borrower's name on any checks, payment instruments, or other forms of payment or security; and (viii) notify all account debtors to pay Agent directly. Borrower hereby appoints Agent as its lawful attorney-in-fact to sign Borrower's name on any documents necessary to perfect or continue the perfection of Agent's security interest in the Collateral regardless of whether an Event of Default has occurred until Payment in Full. Agent's foregoing appointment as Borrower's attorney in fact, and all of Agent's rights and powers, coupled with an interest, are irrevocable until Payment in Full. Agent may, and at the direction of the Required Lenders shall, exercise all rights and remedies with respect to the Collateral under the Loan Documents or otherwise available to it under the UCC and other applicable law, including the right to release, hold, sell, lease, liquidate, collect, realize upon, or otherwise dispose of all or any part of the Collateral and the right to occupy, utilize, process and commingle the Collateral. All Agent's rights and remedies shall be cumulative and not exclusive.

10.2 Collection; Foreclosure. Upon the occurrence and during the continuance of any Event of Default, Agent may, and at the direction of the Required Lenders shall, at any time or from time to time, apply, collect, liquidate, sell in one or more sales, lease or otherwise dispose of, any or all of the Collateral, in its then condition or following any commercially reasonable preparation or processing, in such order as Agent may elect. Any such sale may be made either at public or private sale at its place of business or elsewhere. Borrower agrees that any such public or private sale may occur upon ten (10) calendar days' prior written notice to Borrower. Agent may require Borrower to assemble the Collateral and make it available to Agent at a place designated by Agent that is reasonably convenient to Agent and Borrower. The proceeds of any sale, disposition or other realization upon all or any part of the Collateral shall be applied by Agent in the following order of priorities:

First, to Agent, in an amount equal to the sum of all fees owing to Agent hereunder and under any other Loan Document;

Second, to Agent and Lenders in an amount sufficient to pay in full Agent's and Lenders' reasonable costs and professionals' and advisors' fees and expenses as described in Section 11.12;

Third, to Lenders, ratably, in an amount equal to the sum of all accrued interest owing to Lenders on the Term Loan Advances hereunder;

Fourth, to Lenders, ratably, in an amount equal to the sum of the outstanding principal and premium, if any owing to Lenders from Borrower on the Term Loan Advances hereunder;

Fifth, to Lenders and Agent, ratably (in proportion to all remaining Secured Obligations owing to each), in an amount equal to the sum of all other outstanding and unpaid Secured Obligations (including principal, interest, and the default rate interest set forth in Section 2.4, if required under this Agreement), in such order and priority as Agent may choose in its sole discretion; and

Finally, after the full and final Payment in Full, to any creditor holding a junior Lien on the Collateral, or to Borrower or its representatives or as a court of competent jurisdiction may direct.

Agent shall be deemed to have acted reasonably in the custody, preservation and disposition of any of the Collateral if it complies with the obligations of a secured party under the UCC.

10.3 No Waiver. Agent shall be under no obligation to marshal any of the Collateral for the benefit of Borrower or any other Person, and Borrower expressly waives all rights, if any, to require Agent to marshal any Collateral.

10.4 Waivers. Borrower waives demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Agent on which Borrower is liable.

10.5 Cumulative Remedies. The rights, powers and remedies of Agent hereunder shall be in addition to all rights, powers and remedies given by statute or rule of law and are cumulative. The exercise of any one or more of the rights, powers and remedies provided herein shall not be construed as a waiver of or election of remedies with respect to any other rights, powers and remedies of Agent.

SECTION 11. MISCELLANEOUS

11.1 Severability. Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement shall be prohibited by or invalid under such law, such provision shall be ineffective only to the extent and duration of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Agreement.

11.2 Notice. Except as otherwise provided herein, any notice, demand, request, consent, approval, declaration, service of process or other communication (including the delivery of Financial Statements) that is required, contemplated, or permitted under the Loan Documents or with respect to the subject matter hereof shall be in writing, and shall be deemed to have been validly served, given, delivered, and received upon the earlier of: (i) the day of transmission by electronic mail or hand delivery or delivery by an overnight express service or overnight mail delivery service; or (ii) the third calendar day after deposit in the United States of America mails, with proper first class postage prepaid, in each case addressed to the party to be notified as follows:

(a) If to Agent:

HERCULES CAPITAL, INC.
Legal Department
Attention: Chief Legal Officer, [**]
1 North B Street, Suite 2000
San Mateo, CA 94401
email: [**]
Telephone: 650-289-3060

(b) If to Lenders:

HERCULES CAPITAL, INC.
Legal Department
Attention: Chief Legal Officer, [**]
1 North B Street, Suite 2000
San Mateo, CA 94401
email: [**]
Telephone: 650-289-3060

(c) If to Borrower:

DYNE THERAPEUTICS, INC.
Attention: Erick Lucera, Chief Financial Officer
1560 Trapelo Road
Waltham, MA 02451
email: [**]

With a copy (which shall not constitute notice) to:

WilmerHale
1225 Seventeenth St., Suite 2600
Denver, CO 80202 USA
Attn: Nathan J. Moore
Email: Nathan.Moore@Wilmerhale.com
Telephone: (720) 598-3462

or to such other address as each party may designate for itself by like notice.

11.3 Entire Agreement; Amendments.

(a) This Agreement and the other Loan Documents constitute the entire agreement and understanding of the parties hereto in respect of the subject matter hereof and thereof, and supersede and replace in their entirety any prior proposals, term sheets, non-disclosure or confidentiality agreements, letters, negotiations or other documents or agreements, whether written or oral, with respect to the subject matter hereof or thereof (including Agent's revised proposal letter dated [**] and the Non-Disclosure Agreement).

(b) Neither this Agreement, any other Loan Document, nor any terms hereof or thereof may be amended, supplemented or modified except in accordance with the provisions of this Section 11.3(b). The Required Lenders and Loan Parties party to the relevant Loan Document may, or, with the written consent of the Required Lenders, Agent and Loan Parties party to the relevant Loan Document may, from time to time, (i) enter into written amendments, supplements or modifications hereto and to the other Loan Documents for the purpose of adding any provisions to this Agreement or the other Loan Documents or changing in any manner the rights of Lenders or of Loan Parties hereunder or thereunder or (ii) waive, on such terms and conditions as the Required Lenders or Agent, as the case may be, may specify in such instrument, any of the requirements of this Agreement or the other Loan Documents or any Default or Event of Default and its consequences; provided, however, that no such waiver and no such amendment, supplement or modification shall (A) forgive the principal amount or extend the final scheduled date of maturity of any Loan, extend the scheduled date of any amortization payment in respect of any Term Loan Advance, reduce the stated rate of any interest (or fee payable hereunder) or extend the scheduled date of any payment thereof, in each case without the written consent of each Lender directly

affected thereby; (B) eliminate or reduce the voting rights of any Lender under this Section 11.3(b) without the written consent of such Lender; (C) reduce any percentage specified in the definition of Required Lenders, consent to the assignment or transfer by Loan Parties of any of its rights and obligations under this Agreement and the other Loan Documents, release all or substantially all of the Collateral or release a Loan Party from its obligations under the Loan Documents, in each case without the written consent of all Lenders; or (D) amend, modify or waive any provision of Section 11.18 or Addendum 4 without the written consent of Agent. Any such waiver and any such amendment, supplement or modification shall apply equally to each Lender and shall be binding upon the applicable Loan Parties, Lenders, Agent and all future holders of the Loans.

11.4 No Strict Construction. The parties hereto have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the parties hereto and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any provisions of this Agreement.

11.5 No Waiver. The powers conferred upon Agent and Lenders by this Agreement are solely to protect their rights hereunder and under the other Loan Documents and their interest in the Collateral and shall not impose any duty upon Agent or Lenders to exercise any such powers. No omission or delay by Agent or Lenders at any time to enforce any right or remedy reserved to them, or to require performance of any of the terms, covenants or provisions hereof by Borrower at any time designated, shall be a waiver of any such right or remedy to which Agent or Lenders are entitled, nor shall it in any way affect the right of Agent or Lenders to enforce such provisions thereafter.

11.6 Survival. All agreements, representations and warranties contained in this Agreement and the other Loan Documents or in any document delivered pursuant hereto or thereto shall be for the benefit of Agent and Lenders and shall survive the execution and delivery of this Agreement. Sections 6.3, 11.9, 11.11, 11.14, 11.15, 11.17 and 11.18 shall survive the termination of this Agreement.

11.7 Successors and Assigns. The provisions of this Agreement and the other Loan Documents shall inure to the benefit of and be binding on Borrower and its permitted assigns (if any). No Loan Party shall assign its obligations under this Agreement or any of the other Loan Documents without Agent's express prior written consent, and any such attempted assignment shall be void and of no effect. Agent and Lenders may not assign, transfer, or endorse its rights hereunder and under the other Loan Documents without the prior written consent of Borrower (not to be unreasonably withheld, conditioned or delayed); provided that no such consent shall be required for any such assignment, transfer or endorsement (x) after the occurrence of an Event of Default that is continuing, or (y) to Agent or a Lender or Affiliate of any Lender or Agent, and all of such rights shall inure to the benefit of Agent's and Lenders' successors and assigns. Notwithstanding the foregoing, (x) in connection with any assignment by a Lender as a result of a forced divestiture at the request of any regulatory agency, the restrictions set forth herein shall not apply and Agent and Lenders may assign, transfer or endorse its rights hereunder and under the other Loan Documents to any Person or party and (y) in connection with a Lender's own financing or securitization transactions, the restrictions set forth herein shall not apply and Agent and Lenders may assign, transfer or endorse its rights hereunder and under the other Loan Documents to any Person or party providing such financing or formed to undertake such securitization transaction and any transferee of such Person or party upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; provided that no such sale, transfer, pledge or assignment under this clause (y) shall release such Lender from any of its obligations hereunder

or substitute any such Person or party for such Lender as a party hereto until Agent shall have received and accepted an effective assignment agreement from such Person or party in form satisfactory to Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such assignee as Agent reasonably shall require. Agent, acting solely for this purpose as a non-fiduciary agent of Borrower, shall maintain at one of its offices in the United States a register for the recordation of the names and addresses of Lender(s), and the Term Commitments of, and principal amounts (and stated interest) of the Loans owing to, each Lender pursuant to the terms hereof from time to time (the "Register"). The entries in the Register shall be conclusive absent manifest error, and Borrower, Agent and Lender(s) shall treat each Person whose name is recorded in the Register pursuant to the terms hereof as a Lender hereunder for all purposes of this Agreement. The Register shall be available for inspection by Borrower and any Lender, at any reasonable time and from time to time upon reasonable prior notice.

11.8 Participations. Each Lender that sells a participation shall, acting solely for this purpose as a non-fiduciary agent of Borrower, maintain a register on which it enters the name and address of each participant and the principal amounts (and stated interest) of each participant's interest in the Loans or other obligations under the Loan Documents (the "Participant Register"); provided that no Lender shall have any obligation to disclose all or any portion of the Participant Register (including the identity of any participant or any information relating to a participant's interest in any commitments, loans, its other obligations under any Loan Document) to any Person except to the extent that such disclosure is necessary to establish that such commitment, loan, letter of credit or other obligation is in registered form under Section 5f.103-1(c) of the United States Treasury Regulations. The entries in the Participant Register shall be conclusive absent manifest error, and such Lender shall treat each Person whose name is recorded in the Participant Register as the owner of such participation for all purposes of this Agreement notwithstanding any notice to the contrary. For the avoidance of doubt, Agent (in its capacity as Agent) shall have no responsibility for maintaining a Participant Register. Borrower agrees that each participant shall be entitled to the benefits of the provisions in Addendum 1 attached hereto (subject to the requirements and limitations therein, including the requirements under Section 7 of Addendum 1 attached hereto (it being understood that the documentation required under Section 7 of Addendum 1 attached hereto shall be delivered to the participating Lender)) to the same extent as if it were a Lender and had acquired its interest by assignment pursuant to Section 11.7; provided that (A) such participant shall not be entitled to receive any greater payment under Addendum 1 attached hereto, with respect to any participation, than its participating Lender would have been entitled to receive, except to the extent such entitlement to receive a greater payment results from a change in law that occurs after the participant acquired the applicable participation, (B) each Lender agrees, at Borrower's request and expense, to use reasonable efforts to cooperate with Borrower to effectuate the provisions of Addendum 1 with respect to its participant(s), (C) no such participation shall release any Lender from any of its obligations under any Loan Document and (D) if no Event of Default has occurred and is continuing, no participant may be a direct competitor of Borrower (as reasonably determined by Agent).

11.9 Governing Law. This Agreement and the other Loan Documents have been negotiated and delivered to Agent and Lenders in the State of New York, and shall have been accepted by Agent and Lenders in the State of New York. Payment to Agent and Lenders by Borrower of the Secured Obligations is due in the State of New York. This Agreement and the other Loan Documents shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, excluding conflict of laws principles that would cause the application of laws of any other jurisdiction.

11.10 Consent to Jurisdiction and Venue. All judicial proceedings (to the extent that the reference requirement of Section 11.11 is not applicable) arising in or under or related to this Agreement or any of the other Loan Documents may be brought in any state or federal court located in the State of New York. By execution and delivery of this Agreement, each party hereto generally and unconditionally: (a) consents to nonexclusive personal jurisdiction of the United States District Court for the Southern District of New York; (b) waives any objection as to jurisdiction or venue in the United States District Court for the Southern District of New York; (c) agrees not to assert any defense based on lack of jurisdiction or venue in the aforesaid courts; and (d) irrevocably agrees to be bound by any judgment rendered thereby in connection with this Agreement or the other Loan Documents. Service of process on any party hereto in any action arising out of or relating to this Agreement shall be effective if given in accordance with the requirements for notice set forth in Section 11.2, and shall be deemed effective and received as set forth in Section 11.2. Nothing herein shall affect the right to serve process in any other manner permitted by law or shall limit the right of either party to bring proceedings in the courts of any other jurisdiction.

11.11 Mutual Waiver of Jury Trial

. Because disputes arising in connection with complex financial transactions are most quickly and economically resolved by an experienced and expert Person and the parties wish applicable state and federal laws to apply (rather than arbitration rules), the parties desire that their disputes be resolved by a judge applying such applicable laws. EACH OF BORROWER, AGENT AND LENDERS SPECIFICALLY WAIVES ANY RIGHT IT MAY HAVE TO TRIAL BY JURY OF ANY CAUSE OF ACTION, CLAIM, CROSS-CLAIM, COUNTERCLAIM, THIRD PARTY CLAIM OR ANY OTHER CLAIM (COLLECTIVELY, "CLAIMS") ASSERTED BY BORROWER AGAINST AGENT, LENDERS OR THEIR RESPECTIVE ASSIGNEE OR BY AGENT, LENDERS OR THEIR RESPECTIVE ASSIGNEE AGAINST BORROWER. This waiver extends to all such Claims, including Claims that involve Persons other than Agent, Borrower or any Lenders; Claims that arise out of or are in any way connected to the relationship among Borrower, Agent and Lenders; and any Claims for damages, breach of contract, tort, specific performance, or any equitable or legal relief of any kind, arising out of this Agreement, any other Loan Document.

11.12 Professional Fees. Borrower promises to pay Agent's and Lenders' reasonable and documented out-of-pocket fees and expenses necessary to finalize the Loan Documents, including but not limited to reasonable and documented out-of-pocket attorneys' fees, UCC searches, filing costs, and other related expenses. In addition, Borrower promises to pay any and all reasonable and documented out-of-pocket attorneys' and other reasonable and documented out-of-pocket professionals' fees (excluding costs of in-house counsel) and reasonable and documented out-of-pocket expenses incurred by Agent and Lenders after the Closing Date in connection with or related to: (a) the Loan; (b) the administration, collection, or enforcement of the Loan; (c) the amendment or modification of the Loan Documents; (d) any waiver, consent, release, or termination under the Loan Documents; (e) the protection, preservation, audit, field exam, sale, lease, liquidation, or disposition of Collateral or the exercise of remedies with respect to the Collateral; (f) any legal, litigation, administrative, arbitration, or out of court proceeding in connection with or related to Borrower or the Collateral, and any appeal or review thereof; and (g) any bankruptcy, restructuring, reorganization, assignment for the benefit of creditors, workout, foreclosure, or other action related to Borrower, the Collateral, the Loan Documents, including representing Agent or Lenders in any adversary proceeding or contested matter commenced or continued by or on behalf of Borrower's estate, and any appeal or review thereof.

11.13 Confidentiality. Agent and Lenders acknowledge that items of Collateral and information provided to Agent and Lenders by Borrower are confidential and proprietary information of Borrower, if and to the extent such information either (x) is marked as confidential by Borrower at the time of disclosure, or (y) should reasonably be understood to be confidential (the "Confidential Information"). Accordingly, Agent and Lenders agree that any Confidential Information it may obtain in connection with the Loan Documents or in the course of acquiring, administering, or perfecting Agent's security interest in the Collateral shall not be disclosed to any other Person or entity in any manner whatsoever, in whole or in part, without the prior written consent of Borrower, except that Agent and Lenders may disclose any such information: (a) to its Affiliates and its partners, investors, lenders, directors, officers, employees, agents, advisors, counsel, accountants, representatives and other professional advisors if Agent or Lenders in their sole discretion determine that any such party should have access to such information in connection with such party's responsibilities in connection with the Loan or this Agreement and, provided that such recipient of such Confidential Information either (i) agrees to be bound by the confidentiality provisions of this Section or (ii) is otherwise subject to confidentiality restrictions that reasonably protect against the disclosure of Confidential Information and in any case are not materially less restrictive than this Section; (b) if such information is generally available to the public or to the extent such information becomes publicly available other than as a result of a breach of this Section or becomes available to Agent or any Lender, or any of their respective Affiliates on a non-confidential basis from a source other than Borrower; (c) if required or appropriate in any report, statement or testimony required by law or order of any Governmental Authority to be submitted to any Governmental Authority having or claiming to have jurisdiction over Agent or Lenders and any rating agency; (d) if required or appropriate in response to any summons or subpoena or in connection with any litigation, to the extent permitted or deemed advisable by Agent's or Lenders' counsel; (e) to comply with any legal requirement or law applicable to Agent or Lenders or demanded by any Governmental Authority; (f) to the extent reasonably necessary in connection with the exercise of, or preparing to exercise, or the enforcement of, or preparing to enforce, any right or remedy under any Loan Document (including Agent's sale, lease, or other disposition of Collateral after the occurrence and during the continuance of an Event of Default), or any action or proceeding relating to any Loan Document; (g) to any participant or assignee of Agent or Lenders or any bona fide prospective participant or assignee, provided, that such participant or assignee or prospective participant or assignee is subject to confidentiality restrictions that reasonably protect against the disclosure of Confidential Information which are not materially less restrictive than this Section; (h) to any investor or bona fide potential investor (and each of their respective Affiliates or clients) in Agent or Lenders (or each of their respective Affiliates); provided that such investor, potential investor, Affiliate or client is subject to confidentiality obligations with respect to the Confidential Information which are not materially less restrictive than this Section; (i) otherwise to the extent consisting of general portfolio information that does not identify Borrower; or (j) otherwise with the prior written consent of Borrower; provided, that any disclosure made in violation of this Agreement shall not affect the obligations of Borrower or any of its Affiliates or any guarantor under this Agreement or the other Loan Documents. Agent's and Lenders' obligations under this Section 11.13 shall supersede all of their respective obligations under the Non-Disclosure Agreement.

11.14 Assignment of Rights. Borrower acknowledges and understands that Agent or Lenders may, subject to Section 11.7, sell and assign all or part of its interest hereunder and under the Loan Documents to any Person or entity (an "Assignee"). After such assignment the term "Agent" or "Lender" as used in the Loan Documents shall mean and include such Assignee, and such Assignee shall be vested with all rights, powers and remedies of Agent and Lenders hereunder with respect to the interest so assigned; but with respect to any such interest not so transferred, Agent and Lenders shall retain all rights, powers and remedies hereby given. No such assignment by Agent or Lenders shall relieve Borrower of any of its obligations hereunder. Lenders agree that in the

event of any transfer by it of the promissory note(s) (if any), it will endorse thereon a notation as to the portion of the principal of the promissory note(s), which shall have been paid at the time of such transfer and as to the date to which interest shall have been last paid thereon.

11.15 Revival of Secured Obligations. This Agreement and the Loan Documents shall remain in full force and effect and continue to be effective if any petition is filed by or against Borrower for liquidation or reorganization, if Borrower becomes insolvent or makes an assignment for the benefit of creditors, if a receiver or trustee is appointed for all or any significant part of Borrower's assets, or if any payment or transfer of Collateral is recovered from Agent or Lenders. The Loan Documents and the Secured Obligations and Collateral security shall continue to be effective, or shall be revived or reinstated, as the case may be, if at any time payment and performance of the Secured Obligations or any transfer of Collateral to Agent, or any part thereof is rescinded, avoided or avoidable, reduced in amount, or must otherwise be restored or returned by, or is recovered from, Agent, Lenders or by any obligee of the Secured Obligations, whether as a "voidable preference," "fraudulent conveyance," or otherwise, all as though such payment, performance, or transfer of Collateral had not been made. In the event that any payment, or any part thereof, is rescinded, reduced, avoided, avoidable, restored, returned, or recovered, the Loan Documents and the Secured Obligations shall be deemed, without any further action or documentation, to have been revived and reinstated except to the extent of the full, final, and indefeasible payment to Agent or Lenders in Cash.

11.16 Counterparts. This Agreement and any amendments, waivers, consents or supplements hereto may be executed in any number of counterparts, and by different parties hereto in separate counterparts, each of which when so delivered shall be deemed an original, but all of which counterparts shall constitute but one and the same instrument.

11.17 No Third-Party Beneficiaries. No provisions of the Loan Documents are intended, nor will be interpreted, to provide or create any third-party beneficiary rights or any other rights of any kind in any Person other than Agent, Lenders and Borrower unless specifically provided otherwise herein, and, except as otherwise so provided, all provisions of the Loan Documents will be personal and solely among Agent, Lenders and the Loan Parties party thereto.

11.18 Agency. Agent and each Lender hereby agree to the terms and conditions set forth on Addendum 4 attached hereto. Borrower acknowledges and agrees to the terms and conditions set forth on Addendum 4 attached hereto.

11.19 Publicity. None of the parties hereto nor any of its respective member businesses and Affiliates shall, without the other parties' prior written consent (which shall not be unreasonably withheld or delayed), publicize or use (a) the other party's name (including a brief description of the relationship among the parties hereto), logo or hyperlink to such other parties' web site, separately or together, in written and oral presentations, advertising, promotional and marketing materials, client lists, public relations materials or on its web site (together, the "Publicity Materials"); (b) the names of officers of such other parties in the Publicity Materials; and (c) such other parties' name, trademarks, servicemarks in any news or press release concerning such party; provided however, notwithstanding anything to the contrary herein, no consent shall be required to disclose information (i) to the extent necessary to comply with the requests of any regulators, legal requirements or laws applicable to such party, pursuant to any listing agreement with any national securities exchange or the rules and regulations of the Securities and Exchange Commission (so long as such party provides prior notice to the other party hereto to the extent reasonably practicable) and (ii) to comply with Section 11.13.

11.20 Multiple Borrowers. Each Borrower hereby agrees to the terms and conditions set forth on Addendum 5 attached hereto.

11.21 Managerial Assistance. Borrower acknowledges that Hercules Capital, Inc. has elected to be regulated as a business development company under the 1940 Act, and as such is required to make available significant managerial assistance to its portfolio companies. Significant managerial assistance may include, but is not limited to, guidance and counsel concerning the portfolio company's management, operations, business objectives and policies, arrangement of financing, management of relationships with financing sources, recruitment of management personnel and evaluation of acquisition and divestiture opportunities. Borrower hereby acknowledges and agrees that it may request such assistance at any time from Hercules Capital, Inc. by contacting [**].

11.22 Electronic Execution of Certain Other Documents. The words "execution," "execute", "signed," "signature," and words of like import in or related to any document to be signed in connection with this Agreement and the transactions contemplated hereby (including without limitation assignments, assumptions, amendments, waivers and consents) shall be deemed to include electronic signatures, the electronic matching of assignment terms and contract formations on electronic platforms approved by Agent, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

(SIGNATURES TO FOLLOW)

IN WITNESS WHEREOF, Borrower, Agent and Lenders have duly executed and delivered this Loan and Security Agreement as of the day and year first above written.

BORROWER:

DYNE THERAPEUTICS, INC.

Signature: /s/ Erick Lucera_____

Print Name: Erick Lucera

Title: Chief Financial Officer and Treasurer

Accepted in San Mateo, California:

AGENT:

HERCULES CAPITAL, INC.

Signature:/s/ Seth Meyer_____

Print Name: Seth Meyer

Title: Chief Financial Officer

LENDERS:

HERCULES CAPITAL, INC.

Signature:/s/ Seth Meyer_____

Print Name: Seth Meyer

Title: Chief Financial Officer

HERCULES PRIVATE CREDIT FUND 1 L.P.

By: Hercules Private Global Venture Growth Fund GP I LLC, its General Partner

Signature:/s/ Seth Meyer_____

Print Name: Seth Meyer

Title: Authorized Signatory

HERCULES PRIVATE GLOBAL VENTURE

GROWTH FUND I L.P.

By: Hercules Private Global Venture Growth Fund GP I LLC, its General Partner

Signature:/s/ Seth Meyer_____

Print Name: Seth Meyer

Title: Authorized Signatory

HERCULES VENTURE GROWTH CREDIT

OPPORTUNITIES FUND I L.P.

By: Hercules Venture Growth Credit Opportunities Fund GP I LLC, its General Partner

Signature:/s/ Seth Meyer_____

Print Name: Seth Meyer

Title: Authorized Signatory

HERCULES CAPITAL IV, L.P.

By: Hercules Technology SBIC

Management, LLC, its General Partner

By: Hercules Capital, Inc., its Manager

Signature:/s/ Seth Meyer_____

Print Name: Seth Meyer

Title: Chief Financial Officer

HERCULES SBIC V, L.P.

By: Hercules Technology SBIC

Management, LLC, its General Partner

By: Hercules Capital, Inc., its Manager

Signature:/s/ Seth Meyer_____

Print Name: Seth Meyer

Title: Chief Financial Officer

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ADDENDUM 1 to LOAN AND SECURITY AGREEMENT

TAXES; INCREASED COSTS

1. **Defined Terms**. For purposes of this Addendum 1:

a. "**Connection Income Taxes**" means Other Connection Taxes that are imposed on or measured by net income (however denominated) or that are franchise Taxes or branch profits Taxes.

b. "**Excluded Taxes**" means any of the following Taxes imposed on or with respect to a Recipient or required to be withheld or deducted from a payment to a Recipient, (i) Taxes imposed on or measured by net income (however denominated), franchise Taxes, and branch profits Taxes, in each case, (A) imposed as a result of such Recipient being organized under the laws of, or having its principal office or, in the case of any Lender, its applicable lending office located in, the jurisdiction imposing such Tax (or any political subdivision thereof) or (B) that are Other Connection Taxes, (ii) in the case of a Lender, U.S. federal withholding Taxes imposed on amounts payable to or for the account of such Lender with respect to an applicable interest in a Loan or Term Commitment pursuant to a law in effect on the date on which (A) such Lender acquires such interest in the Loan or Term Commitment or (B) such Lender changes its lending office, except in each case to the extent that, pursuant to Section 2 or Section 4 of this Addendum 1, amounts with respect to such Taxes were payable either to such Lender's assignor immediately before such Lender became a party hereto or to such Lender immediately before it changed its lending office, (iii) Taxes attributable to such Recipient's failure to comply with Section 7 of this Addendum 1 and (iv) any withholding Taxes imposed under FATCA.

c. "**FATCA**" means Sections 1471 through 1474 of the Code, as of the date of this Agreement (or any amended or successor version that is substantively comparable and not materially more onerous to comply with), any current or future regulations or official interpretations thereof, any agreements entered into pursuant to Section 1471(b)(1) of the Code, and any fiscal or regulatory legislation, rules or practices adopted pursuant to any intergovernmental agreement, treaty or convention among Governmental Authorities and implementing such Sections of the Code.

d. "**Foreign Lender**" means a Lender that is not a U.S. Person.

e. "**Indemnified Taxes**" means (i) Taxes, other than Excluded Taxes, imposed on or with respect to any payment made by or on account of any obligation of Borrower under any Loan Document and (ii) to the extent not otherwise described in clause (i), Other Taxes.

f. "**Other Connection Taxes**" means, with respect to any Recipient, Taxes imposed as a result of a present or former connection between such Recipient and the jurisdiction imposing such Tax (other than connections arising from such Recipient having executed, delivered, become a party to, performed its obligations under, received payments under, received or perfected a security interest under, engaged in any other transaction pursuant to or enforced any Loan Document, or sold or assigned an interest in any Loan or Loan Document).

g. "**Other Taxes**" means all present or future stamp, court or documentary, intangible, recording, filing or similar Taxes that arise from any payment made under, from the execution, delivery, performance, enforcement or registration of, from the receipt or perfection of a security interest under, or otherwise with respect to, any Loan Document, except any such Taxes that are Other Connection Taxes imposed with respect to an assignment.

h. "**Recipient**" means Agent or any Lender, as applicable.

i. "**Withholding Agent**" means Borrower and Agent.

2. **Payments Free of Taxes**. Any and all payments by or on account of any obligation of Borrower under any Loan Document shall be made without deduction or withholding for any Taxes, except as required by applicable law. If any applicable law (as determined in the good faith discretion of an applicable Withholding Agent) requires the deduction or withholding of any Tax from any such payment by a Withholding Agent, then the applicable Withholding Agent shall be entitled to make such deduction or withholding and shall timely pay the full amount deducted or withheld to the relevant Governmental Authority in accordance with applicable law and, if such Tax is an Indemnified Tax, then the sum payable by Borrower shall be increased as necessary so that after such deduction or withholding has been made (including such deductions and withholdings applicable to additional sums payable under this Section 2 or Section 4 of this Addendum 1) the applicable Recipient receives an amount equal to the sum it would have received had no such deduction or withholding been made.

3. **Payment of Other Taxes by Borrower**. Borrower shall timely pay to the relevant Governmental Authority in accordance with applicable law, or at the option of Agent timely reimburse it for the payment of, any Other Taxes.

4. **Indemnification by Borrower**. Borrower shall indemnify each Recipient, within ten (10) days after demand therefor, for the full amount of any Indemnified Taxes (including Indemnified Taxes imposed or asserted on or attributable to amounts payable under Section 2 of this Addendum 1 or this Section 4) payable or paid by such Recipient or required to be withheld or deducted from a payment to such Recipient and any reasonable expenses arising therefrom or with respect thereto, whether or not such Indemnified Taxes were correctly or legally imposed or asserted by the relevant Governmental Authority. A certificate describing the amount of such payment or liability delivered to Borrower by a Lender (with a copy to Agent), or by Agent on its own behalf or on behalf of a Lender, shall be conclusive absent manifest error. In addition, Borrower agrees to pay, and to hold Agent and any Lender harmless from, any and all liabilities with respect to, or resulting from any delay in paying, any and all excise, sales or other similar Taxes (excluding Taxes imposed on or measured by the net income of Agent or such Lender) that may be payable or determined to be payable with respect to any of the Collateral or this Agreement.

5. **Indemnification by Lenders**. Each Lender shall severally indemnify Agent, within ten (10) days after demand therefor, for (a) any Indemnified Taxes attributable to such Lender (but only to the extent that Borrower has not already indemnified Agent for such Indemnified Taxes and without limiting the obligation of Borrower to do so), (b) any Taxes attributable to such Lender's failure to comply with the provisions of

Section 11.8 of the Agreement relating to the maintenance of a Participant Register and (c) any Excluded Taxes attributable to such Lender, in each case, that are payable or paid by Agent in connection with any Loan Document, and any reasonable expenses arising therefrom or with respect thereto, whether or not such Taxes were correctly or legally imposed or asserted by the relevant Governmental Authority. A certificate as to the amount of such payment or liability delivered to any Lender by Agent shall be conclusive absent manifest error. Each Lender hereby authorizes Agent to set off and apply any and all amounts at any time owing to such Lender under any Loan Document or otherwise payable by Agent to Lenders from any other source against any amount due to Agent under this Section 5.

6. **Evidence of Payments**. As soon as practicable after any payment of Taxes by Borrower to a Governmental Authority pursuant to the provisions of this Addendum 1, Borrower shall deliver to Agent the original or a certified copy of a receipt issued by such Governmental Authority evidencing such payment, a copy of the return reporting such payment or other evidence of such payment reasonably satisfactory to Agent.

7. **Status of Lenders**.

a. Any Lender that is entitled to an exemption from or reduction of withholding Tax with respect to payments made under any Loan Document shall deliver to Borrower and Agent, at the time or times reasonably requested by Borrower or Agent, such properly completed and executed documentation reasonably requested by Borrower or Agent as will permit such payments to be made without withholding or at a reduced rate of withholding. In addition, any Lender, if reasonably requested by Borrower or Agent, shall deliver such other documentation prescribed by applicable law or reasonably requested by Borrower or Agent as will enable Borrower or Agent to determine whether or not such Lender is subject to backup withholding or information reporting requirements. Notwithstanding anything to the contrary in the preceding two sentences, the completion, execution and submission of such documentation (other than such documentation set forth in Sections 7(b)(i), 7(b)(ii) and 7(b)(iv) of this Addendum 1) shall not be required if in such Lender's reasonable judgment such completion, execution or submission would subject such Lender to any material unreimbursed cost or expense or would materially prejudice the legal or commercial position of such Lender.

b. Without limiting the generality of the foregoing, in the event that Borrower is a U.S. Person,

i. any Lender that is a U.S. Person shall deliver to Borrower and Agent on or prior to the date on which such Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of Borrower or Agent), executed copies of IRS Form W-9 certifying that such Lender is exempt from U.S. federal backup withholding tax;

ii. any Foreign Lender shall, to the extent it is legally entitled to do so, deliver to Borrower and Agent (in such number of copies as shall be requested by the recipient) on or prior to the date on which such Foreign Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of Borrower or Agent), whichever of the following is applicable:

A. in the case of a Foreign Lender claiming the benefits of an income tax treaty to which the United States is a party (x) with respect to payments of interest under any Loan Document, executed copies of IRS Form W-8BEN or IRS Form W-8BEN-E establishing an exemption from, or reduction of, U.S. federal withholding Tax pursuant to the "interest" article of such tax treaty and (y) with respect to any other applicable payments under any Loan Document, IRS Form W-8BEN or IRS Form W-8BEN-E establishing an exemption from, or reduction of, U.S. federal withholding Tax pursuant to the "business profits" or "other income" article of such tax treaty;

B. executed copies of IRS Form W-8ECI;

C. in the case of a Foreign Lender claiming the benefits of the exemption for portfolio interest under Section 881(c) of the Code, (x) a certificate substantially in the form of Exhibit J-1 to the effect that such Foreign Lender is not a "bank" within the meaning of Section 881(c)(3)(A) of the Code, a "10 percent shareholder" of Borrower within the meaning of Section 871(h)(3)(B) of the Code, or a "controlled foreign corporation" related to Borrower as described in Section 881(c)(3)(C) of the Code (a "U.S. Tax Compliance Certificate") and (y) executed copies of IRS Form W-8BEN or IRS Form W-8BEN-E; or

D. to the extent a Foreign Lender is not the beneficial owner, executed copies of IRS Form W-8IMY, accompanied by IRS Form W-8ECI, IRS Form W-8BEN, IRS Form W-8BEN-E, a U.S. Tax Compliance Certificate substantially in the form of Exhibit J-2 or Exhibit J-3, IRS Form W-9, and/or other certification documents from each beneficial owner, as applicable; provided that if the Foreign Lender is a partnership and one or more direct or indirect partners of such Foreign Lender are claiming the portfolio interest exemption, such Foreign Lender may provide a U.S. Tax Compliance Certificate substantially in the form of Exhibit J-4 on behalf of each such direct and indirect partner;

iii. any Foreign Lender shall, to the extent it is legally entitled to do so, deliver to Borrower and Agent (in such number of copies as shall be requested by the recipient) on or prior to the date on which such Foreign Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of Borrower or Agent), executed copies of any other form prescribed by applicable law as a basis for claiming exemption from or a reduction in U.S. federal withholding Tax, duly completed, together with such supplementary documentation as may be prescribed by applicable law to permit Borrower or Agent to determine the withholding or deduction required to be made; and

iv. if a payment made to a Lender under any Loan Document would be subject to U.S. federal withholding Tax imposed by FATCA if such Lender were to fail to comply with the applicable reporting requirements of FATCA (including those contained in Section 1471(b) or 1472(b) of the Code, as applicable), such Lender shall deliver to Borrower and Agent at the time or times prescribed by law and at such time or times reasonably requested by Borrower or Agent such documentation prescribed by applicable law (including as prescribed by Section 1471(b)(3)(C)(i) of the Code) and such additional documentation reasonably requested by Borrower or Agent as may be necessary for Borrower and Agent to comply with their obligations under FATCA and to determine that such Lender has complied with such Lender's obligations under FATCA or to determine the amount, if any, to deduct and withhold from such payment. Solely for purposes of this clause (iv), "FATCA" shall include any amendments made to FATCA after the date of this Agreement.

c. Each Lender agrees that if any form or certification it previously delivered expires or becomes obsolete or inaccurate in any respect, it shall update such form or certification or promptly notify Borrower and Agent in writing of its legal inability to do so.

8. **Treatment of Certain Refunds**. If any party determines, in its sole discretion exercised in good faith, that it has received a refund of any Taxes as to which it has been indemnified pursuant to the provisions of this Addendum 1 (including by the payment of additional amounts pursuant to the provisions of this Addendum 1), it shall pay to the indemnifying party an amount equal to such refund (but only to the extent of indemnity payments made under the provisions of this Addendum 1 with respect to the Taxes giving rise to such refund), net of all out-of-pocket expenses (including Taxes) of such indemnified party and without interest (other than any interest paid by the relevant Governmental Authority with respect to such refund). Such indemnifying party, upon the request of such indemnified party, shall repay to such indemnified party the amount paid over pursuant to this Section 8 (plus any penalties, interest or other charges imposed by the relevant Governmental Authority) in the event that such indemnified party is required to repay such refund to such Governmental Authority. Notwithstanding anything to the contrary in this Section 8, in no event will the indemnified party be required to pay any amount to an indemnifying party pursuant to this Section 8 the payment of which would place the indemnified party in a less favorable net after-Tax position than the indemnified party would have been in if the Tax subject to indemnification and giving rise to such refund had not been deducted, withheld or otherwise imposed and the indemnification payments or additional amounts with respect to such Tax had never been paid. This Section 8 shall not be construed to require any indemnified party to make available its Tax returns (or any other information relating to its Taxes that it deems confidential) to the indemnifying party or any other Person.

9. **Increased Costs**. If any change in applicable law shall subject any Recipient to any Taxes (other than (A) Indemnified Taxes, (B) Taxes described in clauses (ii) through (iv) of the definition of Excluded Taxes and (C) Connection Income Taxes) on its loans, loan principal, commitments, or other obligations, or its deposits, reserves, other liabilities or capital attributable thereto, and the result shall be to increase the cost to such Recipient of making, converting to, continuing or maintaining any Term Loan Advance or of maintaining its obligation to make any such Loan, or to reduce the amount of any sum received or receivable by such Recipient (whether of principal, interest or any other amount), then, upon the request of such Recipient, Borrower will pay to such Recipient such additional amount or amounts as will compensate such Recipient for such additional costs incurred or reduction suffered.

10. **Survival**. Each party's obligations under the provisions of this Addendum 1 shall survive the resignation or replacement of Agent or any assignment of rights by, or the replacement of, a Lender, the termination of the Term Commitments and the repayment, satisfaction or discharge of all obligations under any Loan Document.

ADDENDUM 2 to LOAN AND SECURITY AGREEMENT

Delivery Instructions

The Compliance Certificate shall be uploaded and executed via Lumonic[2]. All other financial reports required to be furnished to Agent pursuant to Section 7.1 shall be submitted via Lumonic.

The Compliance Certificate and other financial reports required to be furnished to Agent pursuant to Section 7.1 may be sent to [**] with a copy to [**], should access to Lumonic be temporarily unavailable.

[2] All references to Lumonic shall be interpreted as the Portfolio Management Software currently in use by Agent. Lumonic can be reached at the following URL: https://lumonic.com/

ADDENDUM 3 to LOAN AND SECURITY AGREEMENT

SBIC

(a) *Borrower's Business*. For purposes of this Addendum 3, Borrower shall be deemed to include its "affiliates" as defined in Title 13 Code of Federal Regulations Section 121.103. Borrower (i) represents and warrants to Agent and Lenders, with respect to subsection 1 below, as of the initial SBA Funding Date, and (ii) represents and warrants to Agent and Lenders, as of each SBA Funding Date and covenants to Agent and Lenders for a period of one year after each SBA Funding Date or for such longer period as set forth below with respect to subsections 2, 3, 4, 5, 6 and 7 below, as follows:

1. Size Status. Borrower's primary NAICS code is 541714 and has less than 250 employees in the aggregate (as determined in accordance with Title 13 Code of Federal Regulations Section 121.106);

2. No Relender. Borrower's primary business activity does not involve, directly or indirectly, providing funds to others, purchasing debt obligations, factoring, or long-term leasing of equipment with no provision for maintenance or repair;

3. No Passive Business. Borrower is engaged in a regular and continuous business operation (excluding the mere receipt of payments such as dividends, rents, lease payments, or royalties). Borrower's employees are carrying on the majority of day to day operations. Borrower will not pass through substantially all of the proceeds of the Loan to another entity;

4. No Real Estate Business. Borrower is not classified under North American Industry Classification System (NAICS) codes 531110 (lessors of residential buildings and dwellings), 531120 (lessors of nonresidential buildings except miniwarehouses), 531190 (lessors of other real estate property), 237210 (land subdivision), or 236117 (new housing for-sale builders). Borrower is not classified under NAICS codes 236118 (residential remodelers), 236210 (industrial building construction), or 236220 (commercial and institutional building construction), if Borrower is primarily engaged in construction or renovation of properties on its own account rather than as a hired contractor. Borrower is not classified under NAICS codes 531210 (offices of real estate agents and brokers), 531311 (residential property managers), 531312 (nonresidential property managers), 531320 (offices of real estate appraisers), or 531390 (other activities related to real estate), unless it derives at least 80 percent of its revenue from non-Affiliate sources. The proceeds of the Loan will not be used to acquire or refinance real property unless Borrower (x) is acquiring an existing property and will use at least 51 percent of the usable square footage for its business purposes; (y) is building or renovating a building and will use at least 67 percent of the usable square footage for its business purposes; or (z) occupies the subject property and uses at least 67 percent of the usable square footage for its business purposes.

5. No Project Finance. Borrower's assets are not intended to be reduced or consumed, generally without replacement, as the life of its business

progresses, and the nature of Borrower's business does not require that a stream of cash payments be made to the business's financing sources, on a basis associated with the continuing sale of assets (e.g., real estate development projects and oil and gas wells). The primary purpose of the Loan is not to fund production of a single item or defined limited number of items, generally over a defined production period, where such production will constitute the majority of the activities of Borrower (e.g., motion pictures and electric generating plants).

6. No Farm Land Purchases. Borrower will not use the proceeds of the Loan to acquire farm land which is or is intended to be used for agricultural or forestry purposes, such as the production of food, fiber, or wood, or is so taxed or zoned.

7. No Foreign Investment. The proceeds of the Loan will not be used substantially for a foreign operation, passed through to a foreign business or used to acquire a foreign business. Borrower will not have, on or within one year after each SBA Funding Date and each other Loan provided by a Lender that is an SBIC more than 49 percent of its employees or tangible assets located outside the United States of America.

(b) *Small Business Administration Documentation*. Agent and Lenders acknowledge that Borrower completed, executed and delivered to Agent prior to each SBA Funding Date SBA Forms 480, 652 and 1031 (Parts A and B) together with a business plan showing Borrower's financial projections (including balance sheets and income and cash flows statements) for the period described therein and a written statement (whether included in the purchase agreement or pursuant to a separate statement) from Agent regarding its intended use of proceeds from the sale of securities to Lenders (the "Use of Proceeds Statement"). Borrower represents and warrants to Agent and Lenders that the information regarding Borrower and its affiliates set forth in the SBA Form 480, Form 652 and Form 1031 and the Use of Proceeds Statement delivered as of each SBA Funding Date is accurate and complete.

(c) *Inspection*. The following covenants contained in this Section (c) are intended to supplement and not to restrict the related provisions of the Loan Documents. Subject to the preceding sentence, Borrower will permit, for so long as Lenders hold any debt or equity securities of Borrower, Agent, Lenders or their representative, at Agent's or Lenders' expense, and examiners of the SBA to visit and inspect the properties and assets of Borrower, to examine its books of account and records, and to discuss Borrower's affairs, finances and accounts with Borrower's officers, senior management and accountants, all at such reasonable times as may be requested by Agent or Lenders or the SBA.

(d) *Annual Assessment*. Upon request of Agent or Lender, promptly after the end of each calendar year (but in any event prior to February 28 of each year) and at such other times as may be reasonably requested by Agent or Lenders, Borrower will deliver to Agent a written assessment of the economic impact of Lenders' investment in Borrower, specifying the full-time equivalent net jobs created and total jobs created or retained in connection with the investment, the impact of the investment on the revenues and profits of Borrower's business and on taxes paid by Borrower and its employees, and such other information as may be required regarding Borrower in connection with the filing of Lenders' SBA Form 468. Lenders will assist Borrower with preparing such assessment. In addition to any other rights granted hereunder, Borrower will grant Agent and Lenders and the SBA access to Borrower's books and records for the purpose of verifying the use

of such proceeds. Borrower also will furnish or cause to be furnished to Agent and Lenders such other information regarding the business, affairs and condition of Borrower as Agent or Lenders may from time to time reasonably request, and such information shall be certified by the President, Chief Executive Officer or Chief Financial Officer of Borrower to the extent requested by Agent or Lender for compliance with the SBIC Act.

(e) *Use of Proceeds.* Borrower will use the proceeds from the Loan only for purposes set forth in Section 7.17. Borrower will deliver to Agent from time to time promptly following Agent's request, a written report, certified as correct by Borrower's Chief Financial Officer, verifying the purposes and amounts for which proceeds from the Loan have been disbursed. Borrower will supply to Agent such additional information and documents as Agent reasonably requests with respect to its use of proceeds and will permit Agent and Lenders and the SBA to have access to any and all Borrower records and information and personnel as Agent deems necessary to verify how such proceeds have been or are being used, and to assure that the proceeds have been used for the purposes specified in Section 7.17.

(f) *Activities and Proceeds*. Neither Borrower nor any of its affiliates (if any) will engage in any activities or use directly or indirectly the proceeds from the Loan for any purpose for which a small business investment company is prohibited from providing funds by the SBIC Act, including 13 C.F.R. §107.720. Borrower shall not, nor shall it cause or permit any of its subsidiaries to, without obtaining the prior written approval of Agent, change Borrower's or any such subsidiary's business activities from that conducted on the date hereof to a business activity from which a licensee under the SBIC Act is prohibited from providing funds by the SBIC Act. Borrower agrees that any such change in its or any such subsidiary's business activities without such prior written consent of Agent shall constitute a material breach of the obligations of Borrower under this Addendum 3.

(g) *Compliance and Resolution.* Borrower agrees that a failure to comply with Borrower's obligations under this Addendum, or any other set of facts or circumstances where it has been asserted by any governmental regulatory agency (or Agent or Lenders believes that there is a substantial risk of such assertion) that Agent, Lenders and their affiliates are not entitled to hold, or exercise any significant right with respect to, any securities issued to Lenders by Borrower, will constitute a breach of the obligations of Borrower under the financing agreements among Borrower, Agent and Lenders. In the event of (i) a failure to comply with Borrower's obligations under this Addendum; or (ii) an assertion by any governmental regulatory agency (or Agent or Lenders believe that there is a substantial risk of such assertion) of a failure to comply with Borrower's obligations under this Addendum, then (i) Agent, Lenders and Borrower will meet and resolve any such issue in good faith to the satisfaction of Borrower, Agent, Lenders, and any governmental regulatory agency, and (ii) upon request of Lenders or Agent, Borrower will cooperate and assist with any assignment of the financing agreements among Hercules Capital IV, L.P. and Hercules SBIC V, L.P., as applicable, and Hercules Capital, Inc.

ADDENDUM 4 to LOAN AND SECURITY AGREEMENT

Agent and Lender Terms

(a) Each Lender hereby irrevocably appoints Hercules Capital, Inc. to act on its behalf as Agent hereunder and under the other Loan Documents and irrevocably authorizes Agent to take such actions on its behalf and to exercise such powers as are delegated to Agent by the terms hereof or thereof, together with such actions and powers as are reasonably incidental thereto. Agent shall have only those duties which are specified in this Agreement and it may perform such duties by or through its agents, representatives or employees. In performing its duties on behalf of Lenders, Agent shall exercise the same care which it would exercise in dealing with loans made for its own account, but it shall not be responsible to any Lender for the execution, effectiveness, genuineness, validity, enforceability, collectability or sufficiency of all or any of the Loan Documents, or for any representations, warranties, recitals or statements made therein or made in any written or oral statement or in any financial or other statements, instruments, reports, certificates or any other documents furnished or delivered in connection herewith or therewith by Agent to any Lender or by or on behalf of Borrower to Agent or any Lender, or be required to ascertain or inquire as to the performance or observance of any of the terms, conditions, provisions, covenants or agreements contained herein or therein, as to the use of the proceeds of the Term Loan Advances, the contents of any certificate, report or other document delivered hereunder or thereunder or in connection herewith or therewith, the validity, enforceability, effectiveness or genuineness of this Agreement, any other Loan Document or any other agreement, instrument or document or the satisfaction of any condition set forth in Section 4 or elsewhere herein, other than to confirm receipt of items expressly required to be delivered to Agent. Agent shall not be responsible for insuring the Collateral or for the payment of any Taxes, assessments, charges or any other charges or liens of any nature whatsoever upon the Collateral or otherwise for the maintenance of the Collateral, except in the event Agent enters into possession of a part or all of the Collateral, in which event Agent shall preserve the part in its possession. Unless the officers of Agent acting in their capacity as officer of Agent on Borrower's account have actual knowledge thereof or have been notified in writing thereof by Lenders, Agent shall not be required to ascertain or inquire as to the existence or possible existence of any Event of Default.

(b) Neither Agent nor any of its officers, directors, employees, attorneys, representatives or agents shall be liable to Lenders for any action taken or omitted hereunder or under any of the other Loan Documents or in connection herewith or therewith unless caused by its or their gross negligence or willful misconduct. No provision of this Agreement or of any other Loan Document shall be deemed to impose any duty or obligation on Agent to perform any act or to exercise any power in any jurisdiction in which it shall be illegal, or shall be deemed to impose any duty or obligation on Agent to perform any act or exercise any right or power if such performance or exercise (a) would subject Agent to a Tax in a jurisdiction where it is not then subject to a Tax or (b) would require Agent to qualify to do business in any jurisdiction where it is not so qualified. Without prejudice to the generality of the foregoing, no Lender shall have any right of action whatsoever against Agent as a result of Agent acting or (where so instructed) refraining from acting under this Agreement or under any of the other Loan Documents in accordance with the instructions of Lenders. Agent shall be entitled to refrain from exercising any power, discretion or authority vested in it under this Agreement unless and until it has obtained the written instructions of Lenders. The agency hereby created shall in no way impair or affect any of the rights and powers of, or impose any duties or obligations upon Agent in its individual capacity. With respect to its participation in the Loan Agreement hereunder, Agent shall have the same rights and powers hereunder as any other Lender and may exercise the same rights and powers as though it were not performing the duties and functions delegated to it hereunder and the term "Lender" or

"Lenders" or any similar term shall unless the context clearly indicates otherwise include Agent in its individual capacity.

(c) Agent may rely, and shall be fully protected in acting, or refraining to act, upon, any resolution, statement, certificate, instrument, opinion, report, notice, request, consent, order, bond or other paper or document that it has no reason to believe to be other than genuine and to have been signed or presented by the proper party or parties or, in the case of cables, telecopies and telexes, to have been sent by the proper party or parties. In the absence of its gross negligence or willful misconduct, Agent may conclusively rely, as to the truth of the statements and the correctness of the opinions expressed therein, upon any certificates or opinions furnished to Agent and conforming to the requirements of this Agreement or any of the other Loan Documents. Agent may consult with counsel, and any opinion or legal advice of such counsel shall be full and complete authorization and protection in respect of any action taken, not taken or suffered by Agent hereunder or under any Loan Documents in accordance therewith. Agent shall have the right at any time to seek instructions concerning the administration of the Collateral from any court of competent jurisdiction. Agent shall not be under any obligation to exercise any of the rights or powers granted to Agent by this Agreement and the other Loan Documents at the request or direction of Lenders unless Agent shall have been provided by Lenders with adequate security and indemnity against the costs, expenses and liabilities that may be incurred by it in compliance with such request or direction.

(d) Each Lender agrees to indemnify Agent in its capacity as such (to the extent not reimbursed by Borrower and without limiting the obligation of Borrower to do so), according to its respective Term Commitment percentages (based upon the total outstanding Term Commitments) in effect on the date on which indemnification is sought under this Addendum 4, from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, costs, expenses or disbursements of any kind whatsoever that may at any time be imposed on, incurred by or asserted against Agent in any way relating to or arising out of, this Agreement, any of the other Loan Documents or any documents contemplated by or referred to herein or therein or the transactions contemplated hereby or thereby or any action taken or omitted by Agent under or in connection with any of the foregoing; The agreements in this Section shall survive the payment of the Loans and all other amounts payable hereunder.

(e) To the extent not reimbursed either by Borrower or from the application of Collateral proceeds pursuant to Section 10.2, a Lender (the "Indemnified Lender") shall be indemnified by the other Lenders (an "Indemnifying Lender"), on a several basis in proportion to each Lender's pro rata portion of the Term Commitment, and each Indemnifying Lender agrees to reimburse the Indemnified Lender for the Indemnifying Lender's pro rata share of the following items (an "Indemnified Payment"):

(i) all reasonable out-of-pocket costs and expenses of the Indemnified Lender incurred by the Indemnified Lender in connection with the discharge of its activities under this Agreement or the Loan Agreement, including reasonable legal expenses and attorneys' fees; provided, that the Indemnified Lender shall consult with the other Lender regarding the incurrence of such costs and expenses at reasonable intervals (but not more often than monthly) and any such reasonable costs and expenses shall be "Claims" hereunder notwithstanding any disagreement by the other Lender as to their incurrence; and

from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, costs, expenses or disbursements of any kind or nature whatsoever, which may be imposed on, incurred by or asserted against the Indemnified Lender in any way

relating to or arising out of this Agreement, or any action taken or omitted by the Indemnified Lender hereunder; provided, however, that the Indemnified Lender shall not be reimbursed or indemnified for an Indemnified Payment, except to the extent that the Indemnified Lender paid more than its ratable share of such payment. All Indemnified Payments as set forth in this clause (e) to an Indemnified Lender are intended to be paid ratably by the other Lender.

(f) [Reserved.]

(g) [Reserved.].

(h) Agent in Its Individual Capacity. The Person serving as Agent hereunder shall have the same rights and powers in its capacity as a Lender as any other Lender and may exercise the same as though it were not Agent and the term "Lender" shall, unless otherwise expressly indicated or unless the context otherwise requires, include each such Person serving as Agent hereunder in its individual capacity.

(i) Exculpatory Provisions. Agent shall have no duties or obligations except those expressly set forth herein and in the other Loan Documents. Without limiting the generality of the foregoing, Agent shall not:

(i) be subject to any fiduciary, advisory or other implied duties, regardless of whether any Default or any Event of Default has occurred and is continuing;

(ii) have any duty to take any discretionary action or exercise any discretionary powers, except discretionary rights and powers expressly contemplated hereby or by the other Loan Documents that Agent is required to exercise as directed in writing by Lenders, provided that Agent shall not be required to take any action that, in its opinion or the opinion of its counsel, may expose Agent to liability or that is contrary to any Loan Document or applicable law; and

(iii) except as expressly set forth herein and in the other Loan Documents, have any duty to disclose, and Agent shall not be liable for the failure to disclose, any information relating to Borrower or any of its Affiliates that is communicated to or obtained by any Person serving as Agent or any of its Affiliates in any capacity.

(j) In connection with any exercise of Enforcement Actions hereunder, neither any Agent nor any Lender or any of its partners, or any of their respective directors, officers, employees, attorneys, accountants, or agents shall be liable as such for any action taken or omitted by it or them, except for its or their own gross negligence or willful misconduct with respect to its duties under this Agreement.

(k) Each Lender and Agent may execute any of its powers and perform any duties hereunder either directly or by or through agents or attorneys-in-fact. Each Lender and Agent shall be entitled to advice of counsel concerning all matters pertaining to such powers and duties. No Lender or Agent shall be responsible for the negligence or misconduct of any agents or attorneys-in-fact selected by it, if the selection of such agents or attorneys-in-fact was done without gross negligence or willful misconduct.

(l) Each Lender agrees that it will make its own independent investigation of the financial condition and affairs of Borrower in connection with the making of Term Loan Advances pursuant to the Loan Agreement and has made and shall continue to make its own appraisal of the

creditworthiness of Borrower. Neither Agent nor any Lender shall have any duty or responsibility either initially or on a continuing basis to make any such investigation or any such appraisal on behalf of all Lenders or to provide the other Lenders with any credit or other information with respect thereto whether coming into its possession before the date hereof or any time or times thereafter and shall further have no responsibility with respect to the accuracy of or the completeness of the information provided to Lenders by Borrower.

ADDENDUM 5 to LOAN AND SECURITY AGREEMENT

Multiple Borrower Terms

(a) Borrower's Agent. Each Borrower hereby irrevocably appoints Company as its agent, attorney-in-fact and legal representative for all purposes, including requesting disbursement of the Term Loan and receiving account statements and other notices and communications to Borrowers (or any of them) from Agent or any Lender. Agent may rely, and shall be fully protected in relying, on any request for the Term Loan Advances, disbursement instruction, report, information or any other notice or communication made or given by Company, whether in its own name or on behalf of one or more of the other Borrowers, and Agent shall not have any obligation to make any inquiry or request any confirmation from or on behalf of any other Borrower as to the binding effect on it of any such request, instruction, report, information, other notice or communication, nor shall the joint and several character of Borrowers' obligations hereunder be affected thereby.

(b) Waivers. Each Borrower hereby waives: (i) any right to require Agent to institute suit against, or to exhaust its rights and remedies against, any other Borrower or any other person, or to proceed against any property of any kind which secures all or any part of the Secured Obligations, or to exercise any right of offset or other right with respect to any reserves, credits or deposit accounts held by or maintained with Agent or any Indebtedness of Agent or any Lender to any other Borrower, or to exercise any other right or power, or pursue any other remedy Agent or any Lender may have; (ii) any defense arising by reason of any disability or other defense of any other Borrower or any guarantor or any endorser, co-maker or other person, or by reason of the cessation from any cause whatsoever of any liability of any other Borrower or any guarantor or any endorser, co-maker or other person, with respect to all or any part of the Secured Obligations, or by reason of any act or omission of Agent or others which directly or indirectly results in the discharge or release of any other Borrower or any guarantor or any other person or any Secured Obligations or any security therefor, whether by operation of law or otherwise; (iii) any defense arising by reason of any failure of Agent to obtain, perfect, maintain or keep in force any Lien on, any property of any Borrower or any other person; (iv) any defense based upon or arising out of any bankruptcy, insolvency, reorganization, arrangement, readjustment of debt, liquidation or dissolution proceeding commenced by or against any other Borrower or any guarantor or any endorser, co-maker or other person, including without limitation any discharge of, or bar against collecting, any of the Secured Obligations (including without limitation any interest thereon), in or as a result of any such proceeding. Until Payment in Full, nothing shall discharge or satisfy the liability of any Borrower hereunder except Payment in Full. If any claim is ever made upon Agent for repayment or recovery of any amount or amounts received by Agent in payment of or on account of any of the Secured Obligations, because of any claim that any such payment constituted a preferential transfer or fraudulent conveyance, or for any other reason whatsoever, and Agent repays all or part of said amount by reason of any judgment, decree or order of any court or administrative body having jurisdiction over Agent or any of its property, or by reason of any settlement or compromise of any such claim effected by Agent with any such claimant (including without limitation the any other Borrower), then and in any such event, each Borrower agrees that any such judgment, decree, order, settlement and compromise shall be binding upon such Borrower, notwithstanding any revocation or release of this Agreement or the cancellation of any note or other instrument evidencing any of the Secured Obligations, or any release of any of the Secured Obligations, and each Borrower shall be and remain liable to Agent and Lenders under this Agreement for the amount so repaid or recovered, to the same extent as if such amount had never

originally been received by Agent or any Lender, and the provisions of this sentence shall survive, and continue in effect, notwithstanding any revocation or release of this Agreement. Each Borrower hereby expressly and unconditionally waives all rights of subrogation, reimbursement and indemnity of every kind against any other Borrower, and all rights of recourse to any assets or property of any other Borrower, and all rights to any collateral or security held for the payment and performance of any Secured Obligations, including (but not limited to) any of the foregoing rights which Borrower may have under any present or future document or agreement with any other Borrower or other person, and including (but not limited to) any of the foregoing rights which any Borrower may have under any equitable doctrine of subrogation, implied contract, or unjust enrichment, or any other equitable or legal doctrine.

(c) Consents. Each Borrower hereby consents and agrees that, without notice (except any notices expressly required by the Loan Documents) to or by Borrower and without affecting or impairing in any way the obligations or liability of Borrower hereunder, Agent may, from time to time before or after revocation of this Agreement, do any one or more of the following in its sole and absolute discretion: (i) accept partial payments of, compromise or settle, renew, extend the time for the payment, discharge, or performance of, refuse to enforce, and release all or any parties to, any or all of the Secured Obligations; (ii) grant any other indulgence to any Borrower or any other Person in respect of any or all of the Secured Obligations or any other matter; (iii) accept, release, waive, surrender, enforce, exchange, modify, impair, or extend the time for the performance, discharge, or payment of, any and all property of any kind securing any or all of the Secured Obligations or any guaranty of any or all of the Secured Obligations, or on which Agent at any time may have a Lien, or refuse to enforce its rights or make any compromise or settlement or agreement therefor in respect of any or all of such property; (iv) substitute or add, or take any action or omit to take any action which results in the release of, any one or more other Borrowers or any endorsers or guarantors of all or any part of the Secured Obligations, including, without limitation one or more parties to this Agreement, regardless of any destruction or impairment of any right of contribution or other right of Borrower; (v) apply any sums received from any other Borrower, any guarantor, endorser, or co-signer, or from the disposition of any Collateral or security, to any Indebtedness whatsoever owing from such person or secured by such Collateral or security, in such manner and order as Agent determines in its sole discretion, and regardless of whether such Indebtedness is part of the Secured Obligations, is secured, or is due and payable. Each Borrower consents and agrees that Agent shall be under no obligation to marshal any assets in favor of Borrower, or against or in payment of any or all of the Secured Obligations. Each Borrower further consents and agrees that Agent shall have no duties or responsibilities whatsoever with respect to any property securing any or all of the Secured Obligations. Without limiting the generality of the foregoing, Agent shall have no obligation to monitor, verify, audit, examine, or obtain or maintain any insurance with respect to, any property securing any or all of the Secured Obligations.

(d) Independent Liability. Each Borrower hereby agrees that one or more successive or concurrent actions may be brought hereon against such Borrower, in the same action in which any other Borrower may be sued or in separate actions, as often as deemed advisable by Agent. Each Borrower is fully aware of the financial condition of each other Borrower and is executing and delivering this Agreement based solely upon its own independent investigation of all matters pertinent hereto, and such Borrower is not relying in any manner upon any representation or statement of Agent or any Lender with respect thereto. Each Borrower represents and warrants that it is in a position to obtain, and each Borrower hereby assumes full responsibility for obtaining, any additional information concerning any other Borrower's financial condition and any other matter pertinent hereto as such Borrower may desire, and such Borrower is not relying upon or expecting

Agent to furnish to it any information now or hereafter in Agent's possession concerning the same or any other matter.

(e) Subordination. All Indebtedness of a Borrower now or hereafter arising held by another Borrower is subordinated to the Secured Obligations and Borrower holding the Indebtedness shall take all actions reasonably requested by Agent to effect, to enforce and to give notice of such subordination.

EXHIBIT K

CERTAIN ECONOMIC TERMS

"Amortization Date"	If neither the First Interest Only Extension Conditions nor the Second Interest Only Extension Conditions are satisfied: July 1, 2028. If the First Interest Only Extension Conditions are satisfied: July 1, 2029. If the Second Interest Only Extension Conditions are satisfied: the Term Loan Maturity Date.
"Approval Milestone I" Satisfaction of each of the following events:	(a) no Event of Default shall have occurred and be continuing; and (b) Borrower shall have delivered evidence satisfactory to Agent (including supporting documents as reasonably requested by Agent) that [**].
"Approval Milestone II" Satisfaction of each of the following events:	(a) no Event of Default shall have occurred and be continuing; and (b) Borrower shall have delivered evidence satisfactory to Agent (including supporting documents as reasonably requested by Agent) that [**].
"**At-the-Market Offering**"	Means sales by Borrower of shares of its capital stock that are (i) offered on a delayed or continuous basis under Rule 415 promulgated under the Act pursuant to an effective registration statement on Form S-3 under the Act, and (ii) sold from time to time at prevailing market prices through a designated broker-dealer pursuant to a written agreement between Borrower and such broker-dealer
"Commercial Milestone" Satisfaction of each of the following events:	(a) no Event of Default shall have occurred and be continuing; and (b) Borrower shall have delivered evidence satisfactory to Agent (including supporting documents as reasonably requested by Agent) that Borrower has generated Net Product Revenue, measured on a trailing three (3) month basis, of at least [**] Dollars ($[**]) for any measuring period ending by or before March 31, 2028.
"Data Milestone I" Satisfaction of each of the following events:	(a) no Event of Default shall have occurred and be continuing; and (b) Borrower shall have delivered evidence satisfactory to Agent (including supporting documents as reasonably requested by Agent) that Borrower has [**].
"Data Milestone II" Satisfaction of each of the following events:	(a) no Event of Default shall have occurred and be continuing; and (b) Borrower shall have delivered evidence satisfactory to Agent (including supporting documents as reasonably requested by Agent) that Borrower has [**].
"Due Diligence Fee"	[**] Dollars ($[**])
"End of Term Charge"	(x) Five and one-half percent (5.50%) ("End of Term Charge Percentage"), *multiplied* by the aggregate original

	principal amount of such Term Loan Advances made hereunder *Minus* (y) the aggregate amount of payments made pursuant to Section 2.6(a)
"Financing Milestone" Satisfaction of each of the following events:	(a) no Event of Default shall have occurred and be continuing; and (b) Borrower shall have delivered evidence satisfactory to Agent (including supporting documents as reasonably requested by Agent) that Borrower has raised an aggregate amount of at least Three Hundred Fifty Million Dollars ($350,000,000) in Qualified Equity Issuance Net Proceeds between June 4, 2025 and December 15, 2026.
"First Interest Only Extension Conditions" Satisfaction of each of the following events:	(a) no Default or Event of Default shall have occurred and be continuing; and (b) Agent's receipt of evidence prior to July 1, 2028, in form and substance reasonably satisfactory to Agent, that the Tranche 2 Milestone has been achieved.
"Initial Facility Charge"	One Million Dollars ($1,000,000).
"Initial Minimum Cash Test Date"	April 1, 2026; provided, that the Initial Minimum Cash Test Date shall be extended to January 1, 2027 if Borrower shall have delivered evidence satisfactory to Agent (including supporting documents as reasonably requested by Agent) that Borrower has raised an aggregate amount of at least Three Hundred Fifty Million Dollars ($350,000,000) in Qualified Equity Issuance Net Proceeds between June 4, 2025 and December 15, 2026.
"Initial Minimum Revenue Test Date"	The date on or after the Initial Revenue Trigger Date on which the amount of the advanced Term Loan Advances is first greater than One Hundred Million Dollars ($100,000,000).
"Initial Revenue Trigger Date"	The date that reporting is due pursuant to Section 7.1(a) or (b) for the first calendar month or quarter, as applicable, which is nine (9) months after the earliest date that Borrower achieves either the Approval Milestone I or the Approval Milestone II.
"Maximum Term Loan Amount"	Two Hundred Seventy-Five Million Dollars ($275,000,000).
"Minimum Advance Amount"	[**] Dollars ($[**]).
"Prepayment Charge"	(a) The outstanding principal amount of each Advance amount being prepaid, *multiplied by* (b) (i) two percent (2.00%), if the principal amount of such Advance amounts are prepaid on or prior to the date which is twelve (12) months following the Closing Date;

	(ii) one and one-half percent (1.50%), if the principal amount of such Advance amounts are prepaid after the date which is twelve (12) months following the Closing Date but on or prior to the date which is twenty-four (24) months following the Closing Date; and (iii) three-quarters of one percent (0.75%), if after the date which is twenty-four (24) months following the Closing Date through the day before the Term Loan Maturity Date.
"Prime Rate"	The greater of (a) the "prime rate" as reported in *The Wall Street Journal* or any successor publication thereto and (b) seven and one-half percent (7.50%).
"Second Interest Only Extension Conditions" Satisfaction of each of the following events:	(a) no Default or Event of Default shall have occurred and be continuing; (b) the First Interest Only Extension Conditions shall have been achieved; and (c) Agent's receipt of evidence prior to July 1, 2029, in form and substance reasonably satisfactory to Agent, that the Tranche 3 Milestone has been achieved.
"Subsequent Financing"	The closing of any broadly marketed equity offering of Borrower (other than sales effected pursuant to any At-the-Market Offering) which becomes effective after the Closing Date and that Borrower reasonably expects to result in aggregate gross proceeds to Borrower of at least Fifty Million Dollars ($50,000,000).
"Subsequent Tranche Facility Charge"	[**] percent ([**]%) of any Advance (other than a Tranche 1 Advance).
"Term Commitment"	The obligation, if any, of any Lender to make a Term Loan Advance to Borrower in a principal amount not to exceed the amount set forth under the heading "Tranche 1 Commitment", "Tranche 2 Commitment", "Tranche 3 Commitment", "Tranche 4 Commitment" or "Tranche 5 Commitment", as the case may be, opposite such Lender's name on Schedule 1.1.
"Term Loan Interest Rate"	A per annum rate of interest equal to the Prime Rate *plus* two and forty-five hundredths percent (2.45%)
"Term Loan Maturity Date"	July 1, 2030.
"Tranche 1 Commitment"	The obligation, if any, of any Lender to make a Term Loan Advance to Borrower in a principal amount not to exceed the amount set forth under the heading Tranche 1 Commitment opposite such Lender's name on Schedule 1.1.
"Tranche 2 Commitment"	The obligation, if any, of any Lender to make a Term Loan Advance to Borrower in a principal amount not to exceed the amount set forth under the heading Tranche 2 Commitment opposite such Lender's name on Schedule 1.1.
"Tranche 2 Milestone"	Borrower's achievement of at least two (2) of the following: (i) the Data Milestone I, (ii) the Data Milestone II, (iii) the Approval Milestone I, and (iv) the Financing Milestone.

"Tranche 3 Commitment"	The obligation, if any, of any Lender, if any, to make a Term Loan Advance to Borrower in a principal amount not to exceed the amount set forth under the heading Tranche 3 Commitment opposite such Lender's name on Schedule 1.1.
"Tranche 3 Commitment Period"	The period beginning on the first date on which Borrower (i) achieves the Tranche 3 Milestone and (ii) draws the entire amount of the Tranche 2 Commitment, and continuing through the earlier to occur of (a) [**], and (b) the date that is ninety (90) days after the first date on which Borrower shall have achieved the Tranche 3 Milestone.
"Tranche 3 Milestone"	Borrower's achievement of (a) the Financing Milestone, and (b) at least two (2) of the following: (i) the Data Milestone II, (ii) the Approval Milestone I, and (iii) the Approval Milestone II.
"Tranche 4 Commitment"	The obligation, if any, of any Lender to make a Term Loan Advance to Borrower in a principal amount not to exceed the amount set forth under the heading Tranche 4 Commitment opposite such Lender's name on Schedule 1.1.
"Tranche 4 Commitment Period"	The period beginning on the first date on which Borrower (i) achieves the Tranche 4 Milestone and (ii) either draws the entire amount of the Tranche 3 Commitment or the Tranche 3 Commitment Period expires, and continuing through the earlier to occur of (a) [**], and (b) the date that is ninety (90) days after the first date on which Borrower shall have achieved the Tranche 4 Milestone.
"Tranche 4 Milestone"	Borrower's achievement of the Tranche 3 Milestone and the Commercial Milestone.
"Tranche 5 Commitment"	The obligation, if any, of any Lender to make a Term Loan Advance to Borrower in a principal amount not to exceed the amount set forth under the heading Tranche 5 Commitment opposite such Lender's name on Schedule 1.1.
"Tranche 5 Commitment Period"	The period beginning on the Closing Date and continuing until the Amortization Date.

SCHEDULE 1.1

COMMITMENTS

LENDERS	TRANCHE 1 COMMITMENT	TRANCHE 2 COMMITMENT	TRANCHE 3 COMMITMENT	TRANCHE 4 COMMITMENT	TRANCHE 5 COMMITMENT*
Hercules Capital, Inc.	[**]	[**]	[**]	[**]	[**]
Hercules Private Credit Fund 1 L.P.	[**]	[**]	[**]	[**]	[**]
Hercules Private Global Venture Growth Fund I L.P.	[**]	[**]	[**]	[**]	[**]
Hercules Venture Growth Credit Opportunities Fund I L.P.	[**]	[**]	[**]	[**]	[**]
Hercules Capital IV, L.P.	[**]	[**]	[**]	[**]	[**]
Hercules SBIC V, L.P.	[**]	[**]	[**]	[**]	[**]
TOTAL COMMITMENTS	$100,000,000	[**]	[**]	[**]	$50,000,000*

[**]

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-277655 on Form S-3 and Registration Statement Nos. 333-253863, 333-248873, 333-263409, 333-270206, 333-277654, 333-279070, 333-285305 and 333-286150 on Form S-8 of our reports dated March 2, 2026, relating to the financial statements of Dyne Therapeutics, Inc. and the effectiveness of Dyne Therapeutics, Inc.'s internal control over financial reporting appearing in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 2, 2026

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John G. Cox, hereby certify that:

1. I have reviewed this Annual Report on Form 10-K of Dyne Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 2, 2026

/s/ John G. Cox
John G. Cox
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Erick Lucera, hereby certify that:

1. I have reviewed this Annual Report on Form 10-K of Dyne Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 2, 2026

/s/ Erick Lucera
Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, John G. Cox, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge, the Annual Report on Form 10-K of Dyne Therapeutics, Inc. for the fiscal year ended December 31, 2025 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in such Form 10-K fairly presents, in all material respects, the financial condition and results of operations of Dyne Therapeutics, Inc.

/s/ John G. Cox
John G. Cox
President and Chief Executive Officer
(Principal Executive Officer)
March 2, 2026

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Erick Lucera, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge, the Annual Report on Form 10-K of Dyne Therapeutics, Inc. for the fiscal year ended December 31, 2025 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in such Form 10-K fairly presents, in all material respects, the financial condition and results of operations of Dyne Therapeutics, Inc.

/s/ Erick Lucera
Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)
March 2, 2026