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

FORM 10-K

☒ **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 001-40215

Instil Bio, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**83-2072195**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
3963 Maple Avenue, Suite 350 Dallas, Texas	**75219**
(Address of Principal Executive Offices)	(Zip Code)

(972) 499-3350

Registrant's telephone number, including area code

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

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, $0.000001 par value per share	TIL	The Nasdaq Stock Market LLC

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 and posted on its corporate web site, if any, 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 files). Yes ☒ No ☐

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

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 7(a)(2)(B) of the Securities 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 ☒

As of June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $83.4 million, based on the closing price of the registrant's common stock on the Nasdaq Stock Market on June 30, 2025 of $20.83 per share.

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date:

Class of Common Stock	Outstanding at
6,781,976 shares of Common Stock, $0.000001 par value per share	March 25, 2026

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission (SEC) subsequent to the date hereof pursuant to Regulation 14A in connection with the registrant's 2026 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K. Such proxy statement will be filed with the SEC not later than 120 days after the conclusion of the registrant's fiscal year ended December 31, 2025.

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Special Note Regarding Forward-Looking Statements

This Annual Report contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, 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. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "might," "intend," "target," "ongoing," "project," "estimate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions intended to identify statements about the future. These statements speak only as of the date of this Annual Report and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by the forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements include, without limitation, statements about:

- our ability to in-license or acquire and develop additional novel therapeutic candidates;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our need for or ability to obtain additional funding;
- our ability to establish or maintain collaborations or strategic relationships;
- our ability to identify, recruit and retain key personnel, including executive officers and members of management;
- our reliance upon intellectual property licensed from third parties and our ability to obtain such licenses on commercially reasonable terms or at all;
- our ability to protect and enforce our intellectual property position for any product candidates we may in-license or acquire, and the scope of such protection;
- our financial performance;
- the period over which we estimate our existing cash, cash equivalents and marketable securities will be sufficient to fund our future operating expenses and capital expenditure requirements;
- our ability to continue as a going concern;
- our competitive position and the development of and projections relating to our competitors or our industry;
- the impact of laws and regulations;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012;
- the impact of economic conditions, including increases in interest rates, inflation, and foreign and domestic tariffs, on the costs of raw materials, wages, manufacturing and clinical trials and on borrowing costs; and
- the timing and anticipated amounts of future tax payments and benefits (including the potential recognition of unrecognized tax benefits), as well as timing of conclusion of tax audits.

You should read this Annual Report and the documents that we have filed as exhibits to this Annual Report completely and 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. We have included important factors in

this Annual Report, particularly in the “Risk Factor Summary” and “Risk Factors” sections, that could cause actual results or events to differ materially from the forward-looking statements that we make.

Risk Factor Summary

Investing in our securities involves a high degree of risk. Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address every aspect of our risk factors, all of the risks that we face, or other factors not presently known to us or that we currently believe are immaterial. Additional discussion of the risks summarized in this Risk Factor Summary, as well as other risks that we face, can be found under the heading "Risk Factors" in Part I of this Annual Report.

Our business is subject to a number of risks of which you should be aware before making a decision to invest in our common stock. These risks include, among others, the following:

- We have incurred significant losses since our inception and have identified an indicator of substantial doubt about our ability to continue as a going concern. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.
- We have a limited operating history and no history of completing any clinical trial or commercializing any product, which may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability.
- We will need substantial additional funding to meet our financial obligations and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to delay or curtail our planned operations and the pursuit of our strategy.
- We currently do not have a product candidate in active development. We have, and we may in the future, engage in strategic transactions to license or otherwise acquire new product candidates or technologies, and we may not be successful in licensing or otherwise acquiring new product candidates, or in developing or commercializing any such product candidates.
- The regulatory approval processes of the U.S. Food and Drug Administration, or FDA, Medicines and Healthcare Products Regulatory Agency, or MHRA, European Medicines Agency, or EMA, and comparable foreign authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain required regulatory approval for any product candidate we may seek to develop, our business will be substantially harmed.
- Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials. Any product candidates we may seek to develop may not have favorable results in later clinical trials, if any, or receive regulatory approval.
- Therapeutic product candidates can be complex and difficult to manufacture. We intend to rely on third parties to produce clinical supply of any product candidates we may seek to develop, and commercial supplies of any approved product. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or any approved products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.
- We face significant competition from other biotechnology and pharmaceutical companies, and from non-profit institutions, which may result in others acquiring, discovering, developing or commercializing products before or more successfully than we do.
- If we or our future licensors are unable to obtain and maintain sufficient patent protection for any product candidate we may seek to develop, or if the scope of the patent protection is not sufficiently broad, third parties, including our potential competitors, could develop and commercialize products similar or identical to ours, and our ability to commercialize such product candidates may be adversely affected.
- Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain.

- We are subject to a variety of stringent and evolving laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and data security, and our actual or perceived failure to comply with them could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits and other adverse business consequences.

Part I

Item 1. Business.

Overview

We are a biotechnology company focused on identifying and advancing innovative therapeutic opportunities.

In January 2026 we announced our wholly owned subsidiary, Axion Bio, Inc., or Axion Bio, was discontinuing development of our former lead product candidate, AXN-2510, a bispecific antibody targeting both programmed death-ligand 1 and the family of vascular endothelial growth factors in solid tumor cancers. Axion Bio in-licensed AXN-2510 from ImmuneOnco Biopharmaceuticals (Shanghai) Inc., or ImmuneOnco, in August 2024. The license and collaboration agreement with ImmuneOnco was terminated in January 2026. Prior to developing AXN-2510, our development efforts were focused on pursuing the development of cell therapies, including our proprietary folate receptor alpha co-stimulatory antigen receptor (CoStAR) tumor infiltrating lymphocyte (TIL) cell therapy for the treatment of cancer.

We are actively seeking to in-license or acquire and develop additional novel therapeutic candidates in diseases with significant unmet medical need.

Our Strategy

Our strategy is to pursue potential acquisitions or in-licensing of therapeutic candidates.

Competition

The biotechnology and pharmaceutical industries are characterized by the rapid evolution of technologies and understanding of disease etiology, intense competition and a strong emphasis on intellectual property. We believe that our approach, strategy and experience provide us with certain competitive advantages. However, we expect substantial competition from many sources, including major pharmaceutical, specialty pharmaceutical, and existing or emerging biotechnology companies. Many of our potential competitors, either alone or through collaborations, have significantly greater financial resources and expertise in identifying acquisition and in-licensing opportunities, research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. These entities also compete with us in recruiting and retaining qualified personnel and, assuming we in-license or acquire one or more new therapeutic product candidates, in establishing clinical trial sites and patient enrollment in clinical trials, as well as in acquiring complementary or necessary technologies. As a result, potential competitors may discover, develop, license or commercialize products before or more successfully than we do.

We could see a reduction or elimination in our potential commercial opportunity if our competitors discover, develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient to administer, are less expensive or with a more favorable label than any product candidate we may develop. Our competitors also may obtain U.S. Food and Drug Administration, or FDA, or other regulatory approval for their drugs more rapidly than we may obtain approval for any product we may in-license or otherwise acquire and subsequently develop, which could result in competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of any product candidates we may license or otherwise acquire, if approved, are likely to be their efficacy, safety, convenience, price and the availability of reimbursement from government and other third-party payors.

Intellectual Property

Our commercial success will likely depend in part on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions, improvements and know-how; defend and enforce patents and other intellectual property; preserve the confidentiality of trade secrets; and operate without infringing or otherwise violating the valid enforceable patents and proprietary rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell or importing products we may license or otherwise

acquire and subsequently develop may depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. With respect to any licensed or company-owned intellectual property we may acquire, we cannot be sure that patents will be granted with respect to any patent applications filed by us, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our commercial products and methods of manufacturing the same. We may rely, in some circumstances, on trade secrets to protect any technology we may license or otherwise acquire. However, trade secrets can be difficult to protect. See "Risk Factors – Risks Related to Our Intellectual Property."

We intend to seek to protect technology, inventions, and other intellectual property that is commercially important to the development of our business by a variety of means, such as seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties. We also intend to seek patent protection or rely upon trade secret rights to protect other technologies that may be used to manufacture and develop novel product candidates. Additional regulatory protection may also be afforded through data exclusivity, market exclusivity and patent term extensions where available.

Government Regulation

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of therapeutic products. If we are successful in licensing-in or otherwise acquiring new therapeutic product candidates, we, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of such product candidates. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Drugs and Biologics Regulation

In the United States, drug and biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and other federal, state, local and foreign statutes and regulations. The process required by the FDA before drugs or biologics may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's Good Laboratory Practice requirements, or GLP;
- submission to the FDA of an Investigational New Drug application, or IND, which must become effective before clinical trials may begin;
- approval by an institutional review board, or IRB, or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practice, or GCP, regulations and any additional requirements for the protection of human research subjects and their health information to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a New Drug Application, or NDA, or Biologic License Application, or a BLA, after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with current Good Manufacturing Practice, or cGMP, and to assure that the facilities, methods and controls are adequate to preserve the

product's continued safety, purity and potency and of selected clinical investigation sites to assess compliance with Good Clinical Practices, or GCPs;

- satisfactory completion of an FDA Advisory Committee review, if applicable;
- potential FDA audit of the nonclinical and clinical study sites that generated the data in support of the NDA or BLA; and
- FDA review and approval of the NDA or BLA to permit commercial marketing of the product for particular indications for use in the United States.

Before testing any product candidate in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs.

Prior to beginning the first clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

For purposes of NDA or BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1—The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- Phase 2—The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3—The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product in the intended therapeutic indication, particularly for long-term safety follow-up. These so-called Phase 4 studies may also be made a condition to approval of the NDA or BLA.

Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

NDA or BLA Submission and Review by the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for one or more indications. The NDA or BLA must include all relevant data available from preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by independent investigators. The submission of an NDA or BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

Within 60 days following submission of the application, the FDA reviews an NDA or BLA submitted to determine if it is substantially complete before the FDA accepts it for filing. The FDA may refuse to file any NDA or BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the NDA or BLA must be resubmitted with the additional information. Once an NDA or BLA has been accepted for filing, the FDA's goal is to review standard applications within ten months after the filing date, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process may also be extended by FDA requests for additional information or clarification. The FDA reviews an NDA or BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may also convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA or BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP and adequate to assure consistent production of the product within required specifications.

After the FDA evaluates an NDA or BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL will describe all of the deficiencies that the FDA has identified in the NDA or BLA, except that where the FDA determines that the data supporting the application are

inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the NDA or BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of an NDA or BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA or BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks, or otherwise limit the scope of any approval. A REMS is a safety strategy implemented to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. For example, the Fast Track program is intended to expedite or facilitate the process for reviewing new products that are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Specifically, new biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request that the FDA designate the product candidate as a Fast Track product at any time during the clinical development of the product. The sponsor of a Fast Track product has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA or BLA is submitted, the product candidate may be eligible for priority review. A Fast Track product may also be eligible for rolling review, where the FDA may consider for review sections of the NDA or BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA or BLA, the FDA agrees to accept sections of the NDA or BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, 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 designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any marketing application for a drug or biologic submitted to the FDA for approval, including a product candidate with a Fast Track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product candidate is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new biological product designated for priority review in an effort to facilitate the review. For

original NDAs or BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

Additionally, product candidates studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires, as a condition for accelerated approval, pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast Track designation, breakthrough therapy designation, priority review, and accelerated approval do not change the standards for approval but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 individuals in the United States and when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for a particular drug or biologic for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full NDA or BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same biological product as defined by the FDA or if our product candidate is determined to be contained within the competitor's product for the same indication or disease.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or, as noted above, if a second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Post-Approval Requirements

Drugs and biologics are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products. Drug and biologic manufacturers and other entities involved in the manufacture and distribution of approved biological products 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 cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Changes to the manufacturing process or facility are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw 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 studies to assess new safety risks; or imposition of distribution restrictions or other restrictions. 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 untitled letters;
- clinical holds on clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of drugs and biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested and approved by the FDA. Such off-label uses are common across medical specialties.

Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Government Regulation Outside of the United States

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical studies and any commercial sales and distribution of any products we may develop. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries. Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical studies or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical study application much like the IND prior to the commencement of human clinical studies.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Other Healthcare Laws

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business and may constrain the financial arrangements and relationships through which we research, as well as, sell, market and distribute any products for which we obtain marketing approval. Such laws include, without limitation, federal and state anti-kickback, fraud and abuse, false claims, data privacy and security and physician and other health care provider transparency laws and regulations. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration (including any kickback, bribe or rebate), 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;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, impose criminal or civil penalties, as applicable, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government (including the Medicare and Medicaid programs) or other third-party payor claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- Health Insurance Portability and Accountability Act of 1996, or HIPAA, established the federal offense of health care fraud, which among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or to 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 statements in connection with the delivery of or payment for healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without the appropriate authorization by entities subject to the law,

such as health plans, healthcare clearinghouses and healthcare providers and their respective business associates and their covered subcontractors;

- the federal the Physician Payments Sunshine Act and its implementing regulations, requires applicable group purchasing organizations and manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the U.S. Department of Health and Human Services, or HHS, information related to "payments or other transfers of value" made in the previous year to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors, other health care professionals (such as nurse practitioners and physician assistants) and teaching hospitals, and information regarding ownership and investment interests held by physicians (as defined above) or their immediate family members; and
- analogous state and foreign laws and regulations, including: state anti-kickback and false claims laws that may apply to our business practices (including research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by state governmental and non-governmental third-party payors, including private insurers); state and local laws that require certain regulatory licenses to manufacture or distribute pharmaceutical products commercially and/or the registration of pharmaceutical sales representatives; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government; state laws that require drug manufacturers to track gifts and other remuneration and items of value provided to healthcare professionals and entities and file reports relating to pricing and marketing information; and state and foreign laws that govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of any available statutory exceptions and safe harbors, it is possible that some of our current and future business activities could be subject to challenge under one or more of such laws.

If our significant operations are found to be in violation of any of such laws or any other governmental regulations that apply, they may be subject to significant penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations, exclusion from participation in federal and state healthcare programs and imprisonment.

Coverage and Reimbursement

Sales of any product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. These third-party payors are increasingly reducing coverage and reimbursement for medical products, drugs and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. For example, the U.S. Department of Health and Human Services, or HHS, imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. HHS has also been empowered to negotiate the price of certain single-source biologics that have been on the market for at least eleven (11) years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures,

could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales.

Healthcare Reform

In the United States, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, each as amended, collectively known as the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry.

Since its enactment, there have been amendments to and judicial and congressional challenges to certain aspects of the ACA. For example, on July 4, 2025, the One Big Beautiful Bill Act, or the OBBBA, was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year, which began in 2013 and will remain in effect until 2032 unless additional Congressional action is taken.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct to consumer platform, or TrumpRx, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again, or MAHA, Commission’s Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager, or PBM, payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers’ global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court’s Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical 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.

Facilities

Our wholly owned subsidiary, Complex Therapeutics LLC, owns a facility in Tarzana, California that is leased to AstraZeneca Pharmaceuticals LP, or AstraZeneca. The facility consists of 128,097 square feet of clinical and commercial manufacturing space.

Our headquarters is located in Dallas, Texas and consists of 5,055 square feet of leased office space under a lease that expires in April 2026. We also lease 7,728 square feet of laboratory and office space in Alderley Park, United Kingdom, under three leases that expire in November 2026.

We believe that our current facilities are adequate for our current needs.

Employees and Human Capital Resources

As of December 31, 2025, we had 17 employees, all of whom were full-time. None of our employees are represented by labor unions or covered by collective bargaining agreements.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Corporate Information

We were incorporated under the laws of the State of Delaware in August of 2018. Our principal executive offices are located at 3963 Maple Avenue, Suite 350, Dallas, Texas 75219 and our telephone number is (972) 499-3350. Our website address is instilbio.com. The information contained on, or accessible through, our website is not incorporated by reference into this prospectus, and you should not consider any information contained in, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common stock. We have included our website in this prospectus solely as an inactive textual reference.

Available Information

Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, will be made available free of charge on our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or SEC. The contents of our website are not incorporated into this Annual Report and our reference to the URL for our website is intended to be an inactive textual reference only. The information contained on, or that can be accessed through, our website is not a part of this document.

Item 1A. Risk Factors

RISK FACTORS

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Annual Report on Form 10-K and those we may make from time to time. You should carefully consider the risks described below, in addition to the other information contained in this Annual Report on Form 10-K and our other public filings. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks Related to our Financial Position and Capital Needs

We have incurred significant losses since our inception and have identified an indicator of substantial doubt about our ability to continue as a going concern. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

Since our inception, we have incurred significant net losses, and we expect to continue to incur significant expenses and operating losses for the foreseeable future. Our net losses were $71.4 million and $74.1 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $726.5 million. We have financed our operations with funds raised in our initial public offering, private placements of convertible preferred stock, rental income, and offerings under our at-the-market offering program to date. We have no products approved for commercialization and have never generated any revenue from product sales. In connection with the preparation of our consolidated financial statements accompanying this Annual Report on Form 10-K, we identified an indicator of substantial doubt about our ability to continue as a going concern.

We expect to continue to incur significant expenses and operating losses over the next several years. We expect that it could be many years, if ever, before we have a commercialized product. Our net losses may fluctuate significantly from quarter to quarter and year to year. In addition to incurring legal, accounting and other expenses in operating as a public company and costs related to shutting down Axion Bio's clinical trial of AXN-2510, we anticipate that our expenses will continue to be significant as we license or otherwise acquire new product candidates, as well as potentially initiate and complete clinical trials of new product candidates, seek regulatory approval for any product candidates that successfully complete clinical trials; scale up our clinical and regulatory capabilities; rely on third parties to manufacture current good manufacturing practices, or cGMP, material for clinical trials or potential commercial sales; establish a commercialization infrastructure and develop internal and external manufacturing and distribution capabilities to commercialize any product candidates for which we may obtain regulatory approval; adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products; maintain, expand and protect the intellectual property portfolio for any product candidates we may seek to develop; hire clinical, manufacturing quality control, regulatory, manufacturing and scientific and administrative personnel; and add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts.

To date, we have not generated any revenue from product sales. Before we can become and remain profitable, we must succeed in licensing or otherwise acquiring one or more product candidates and developing and eventually commercializing such product candidates. This will require us to be successful in a range of challenging activities, including successfully identifying and acquiring or in-licensing one or more new product candidates, completing preclinical testing and clinical trials of any such product candidates, and obtaining regulatory approval, and manufacturing, marketing and selling any product candidates for which we may obtain regulatory approval. We are only in the preliminary stages of identifying potential new product candidates to in-license or acquire or invest in. We may never succeed in any of these activities and, even if we do, may never generate any revenue or revenue that is significant enough to achieve profitability.

Even if we 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 would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain product approvals, diversify our offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We have a limited operating history and no history of completing any clinical trial or commercializing any product, which may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability.

We are a biotechnology company with a limited operating history. Since we commenced operations in 2019, we have not yet demonstrated our ability to successfully complete any clinical trials, obtain regulatory approvals, manufacture a product on a commercial scale, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Consequently, any predictions you make 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.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. For example, several years ago we elected to discontinue our tumor infiltrating lymphocyte development program and our related ITIL-168 and ITIL-306 clinical trials. More recently, in January 2026 we discontinued development of AXN-2510. As part of discontinuing our prior development programs, we have significantly reduced our workforce in recent years. In the event we are successful in licensing or acquiring one or more new product candidates or we seek to develop new product candidates ourselves, we will need to develop clinical, manufacturing, regulatory and commercial capabilities, and we may not be successful in doing so.

We will need substantial additional funding to meet our financial obligations and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to delay or curtail our planned operations and the pursuit of our strategy.

Our operations have consumed substantial amounts of cash since inception. Identifying and licensing or otherwise acquiring promising new product candidates, and subsequently successfully developing any such product candidates is a time-consuming, expensive and uncertain process that takes years to complete, and we may be unsuccessful or never generate the necessary data or results required to obtain regulatory approval and achieve product sales. We expect to continue to incur significant expenses and operating losses over the next several years as we seek to in-license or otherwise acquire new product candidates, initiate clinical trials of any such product candidates ensure a manufacturing supply of any such product candidates and seek marketing approval for any product candidates that successfully complete clinical trials. In addition, any product candidates, if approved, may not achieve commercial success. Our revenue, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. If we obtain marketing approval for any product candidates that we seek to develop, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. We also expect to continue to incur significant expenses associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

As of December 31, 2025, we had cash, cash equivalents, restricted cash and marketable securities of $76.3 million, which consists of $6.6 million in cash and cash equivalents, $0.2 million of restricted cash and $69.5 million in marketable securities. We believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital requirements beyond 2027. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in and progress of efforts to license or otherwise acquire of new product candidates, changes in development activities, and changes in regulation. Our future capital requirements will depend on many factors, including:

- the extent to which we license or otherwise acquire new product candidates and technologies and the cost of any such assets;
- the number and development requirements of product candidates that we may pursue;
- our ability to complete a potential sale of the Tarzana, California facility in an amount sufficient to repay the secured debt encumbering the facility;
- the costs, timing and outcome of regulatory review of any product candidates we may seek to develop;
- our cost of human capital as we expand our capabilities;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales, and distribution, for any product candidates for which we receive marketing approval;

- the revenue, if any, received from commercial sales of product candidates for which we receive marketing approval; and
- the costs of operating as a public company.

We will require substantial additional capital to achieve our business objectives. Additional funds may not be available on a timely basis, on favorable terms, or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. Further, our ability to raise additional capital may be adversely impacted by worsening global economic conditions and the disruptions to and volatility in the credit and financial markets in the United States and worldwide, including those resulting from armed conflicts, U.S.-China trade and political tensions, heightened inflation and fluctuations in interest rates, tariffs, recent and potential future bank failures and supply chain disruptions, among other geopolitical and macroeconomic factors. If we are unable to raise sufficient additional capital, we could be forced to delay acquiring and developing new product candidates or curtail our planned operations and the pursuit of our strategy.

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

We will need to raise substantial additional capital to support our operations and execute on our business strategy. Until such time, if ever, as we can generate substantial revenue, we may finance our cash needs through a combination of equity offerings, government or private party grants, debt financings or license and collaboration agreements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and 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, making capital expenditures or declaring dividends. For example, the agreements governing the term loan contains certain affirmative and negative covenants, including restrictions on incurring additional debt, maintaining a specified minimum net worth and amount of liquid assets, which could limit our operations.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams or product candidates, grant licenses on terms that may not be favorable to us or commit to future payment streams. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

If Complex Therapeutics LLC is unable to meet the conditions to exercise its option to extend the maturity of its term loan and/or is unable to refinance its term loan or raise sufficient capital to repay its term loan at maturity, or otherwise fails to comply with the terms of the loan agreement, including financial covenants, it could result in an event of default.

The term loan agreement between Complex Therapeutics LLC, our wholly owned subsidiary, and Midland National Life Insurance Company related to the refinancing of our construction loans secured by our Tarzana facility and land, or the term loan, is scheduled to reach maturity on January 10, 2027. Complex Therapeutics LLC has the option to extend the maturity date of the term loan by up to one year by giving notice to the lender between 120 and 30 days before the scheduled maturity date, subject to satisfaction of specified conditions, including the absence of any potential default or event of default, compliance with certain financial covenants, and payment of an extension fee and related lender costs. Although we currently expect Complex Therapeutics LLC to be able to satisfy these conditions, there can be no assurance that it will be able to do so at the time the extension option becomes exercisable. Any failure of Complex Therapeutics LLC to satisfy such conditions, or to otherwise refinance the term loan or sell the Tarzana facility for sufficient proceeds to repay the term loan at maturity, or any failure to comply with the loan covenants, could subject it to default.

If Complex Therapeutics LLC is unable to obtain the extension or otherwise refinance the term loan, the full principal balance of the term loan would become due at its current maturity date in January 2027. Based on Complex Therapeutic LLC's existing cash resources and projected lease income, we do not expect it to have sufficient cash on hand to repay the term loan in full at maturity without securing alternative financing or selling the Tarzana facility, neither of which may be available on acceptable terms or at all. If Complex Therapeutics LLC defaults under the loan agreement, the lender will be able to declare all obligations immediately due and payable and take control of its pledged assets, potentially requiring Complex Therapeutics LLC to renegotiate the loan agreement on terms less favorable or suffer worse outcomes. Although the Company has limited obligations related to the term loan and is not a primary obligor of the term loan, any declaration by the lender of an event of default could materially harm our prospects and cause the price of our common stock to decline. In addition, if, among other things, Complex Therapeutics LLC were to file a voluntary bankruptcy petition, an affiliate, officer, director or representative of us or Complex Therapeutics LLC were to file an involuntary bankruptcy petition against Complex Therapeutics LLC or acquiesce or join in an application for the appointment of a custodian, receiver, trustee or examiner for Complex Therapeutics LLC, or Complex Therapeutics LLC were to make an assignment for the benefit of creditors, we will be fully liable for Complex Therapeutics LLC's obligations under the term loan, which could materially harm our financial position and prospects.

We have suffered, and in the future could suffer, additional losses due to impairment charges related to our Tarzana, California facility, and, in the event of a sale of such facility, the proceeds could be less than our carrying value or the amount of the secured debt encumbering the facility.

To date, we have recorded significant impairment losses on long-lived assets related to our Tarzana, California facility. Most recently, during the year ended December 31, 2025, we recorded aggregate impairment losses on long-lived assets held for sale of $16.6 million related to the Tarzana facility. We may suffer additional impairment losses related to the Tarzana facility. In addition, in the event the Tarzana facility is sold, we may not recover its carrying value, and we may suffer additional impairment losses. Further, it is possible that we will not be able to sell the facility for an amount equal to or greater than the amount of secured debt encumbering the facility.

Risks Related to the Development of Product Candidates

We currently have no product candidate in active development. We have, and we may in the future, engage in strategic transactions to license or otherwise acquire new product candidates or technologies, and we may not be successful in developing or commercializing any such product candidates.

Currently we do not have any product candidate in active development. We do not have any products that are approved for commercial sale, and we may never be able to license or acquire, develop or commercialize any marketable products. We are seeking to engage in strategic transactions to in-license or acquire and develop therapeutic assets for diseases with significant unmet need. We may not be able to identify, in-license or otherwise acquire, and subsequently develop, new product candidates. The licensing or acquisition of third-party intellectual property rights is a competitive area, and more established or more attractive companies may pursue strategies to license or acquire third-party intellectual property rights or assets that we may consider attractive for further development. These companies may have a competitive advantage over us due to their size, capital resources and/or greater clinical development, manufacturing and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us, and companies that do not perceive us to be a potential competitor may be reluctant to consider licensing to us given our lack of relevant meaningful experience. In addition, the process of identifying new product candidates and technologies that may be available to acquire or in-license and assessing their potential and value is difficult and time-consuming. Even if we identify suitable candidates to license or acquire, negotiating strategic transactions is time-consuming. 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 or at all. Even if we are successful in in our efforts to license or acquire product candidates, the potential product candidates that we identify may not be suitable for clinical development. For example, product candidates may be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be successfully developed, much less receive marketing approval and achieve market acceptance. We may not be successful in developing or commercializing any product candidate we may license or otherwise acquire and seek to develop. If we do not successfully develop and commercialize product candidates, we

will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

If we are unable to successfully develop, receive regulatory approval for and commercialize product candidates for the indications we seek, or experience significant delays in doing so, our business will be harmed.

We currently have no product candidate in active development or any products approved for commercial sale. As a company, we have no prior experience completing any clinical trials; we have limited experience in preparing, submitting and prosecuting regulatory filings and we have not previously submitted an NDA or BLA, for any product candidate. Any product candidate that we are able to in-license or otherwise acquire will likely require additional preclinical and/or clinical development, regulatory approval, obtaining manufacturing supply, capacity and expertise, building a commercial organization or successfully outsourcing commercialization, substantial investment and significant marketing efforts before we generate any revenue from product sales. We do not have any products that are approved for commercial sale, and we may never be able to develop or commercialize marketable products.

Our ability to generate revenue from any product candidates which we may seek to develop, which we do not expect will occur for many years, if ever, will depend heavily on the successful development, regulatory approval and eventual commercialization of one or more product candidates. The success of any product candidates that we may seek to develop will depend on several factors, including:

- identifying and successfully licensing or otherwise acquiring promising product candidates;
- timely and successful completion of preclinical studies and clinical trials;
- effective INDs from the FDA or comparable foreign applications that allow commencement of clinical trials for such product candidates;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- successful enrollment and completion of clinical trials, including under the FDA's current Good Clinical Practices, or GCPs, and current Good Laboratory Practices;
- successful development of, or making arrangements with third-party manufacturers for manufacturing product candidates;
- receipt of timely marketing approvals from applicable regulatory authorities;
- launching commercial sales of products, if approved, whether alone or in collaboration with others;
- acceptance of the benefits and use of our products, including method of administration, if approved, by patients, the medical community and third-party payors, for their approved indications;
- the prevalence and severity of adverse events experienced with any product candidates;
- the availability, perceived advantages, cost, safety and efficacy of alternative therapies for any product candidate, and any indications for such product candidate, that we may seek to develop;
- our ability to produce any product candidates we develop on a commercial scale;
- obtaining and maintaining patent, trademark and trade secret protection and regulatory exclusivity for any product candidates we may seek to develop and otherwise protecting our rights in our intellectual property portfolio;
- maintaining compliance with regulatory requirements, including cGMPs, and complying effectively with other procedures;
- obtaining and maintaining third-party coverage and adequate reimbursement and patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement; and

- maintaining a continued acceptable safety, tolerability and efficacy profile of the products following approval.

If we are not successful with respect to 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 seek to develop, which would materially harm our business. If we do not receive marketing approvals for any product candidate we develop, we may not be able to continue our operations. At any time, we may decide to discontinue the development of, or not to commercialize, a product candidate, such as our past decision to discontinue our ITIL-168, ITIL-306 and AXN-2510 development programs. If we terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have missed the opportunity to allocate those resources to potentially more productive uses.

Clinical trials are expensive, time-consuming, difficult to design and implement and involve an uncertain outcome. Further, we may encounter substantial delays in completing the development of any product candidate we may seek to develop.

The clinical trials and manufacturing of product candidates are, and the manufacturing and marketing of products, if approved, will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market any product candidates. Before obtaining regulatory approvals for the commercial sale of any product candidates we may seek to develop, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that such product candidates are both safe and effective for use in each target indication. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Clinical trials are expensive and can take many years to complete, and their outcomes are inherently uncertain. We cannot guarantee that any clinical trials we or a collaborator may conduct of any product candidates we may seek to develop will be conducted as planned or completed on schedule, if at all. Failure can occur at any time during the clinical trial process. Even if clinical trials are completed as planned, we cannot be certain that their results will support the safety and effectiveness of any product candidates for their targeted indications or support continued clinical development of such product candidates. Our clinical trials may not be successful.

In addition, even if we successfully complete clinical trials, we cannot guarantee that the FDA, MHRA, EMA or other comparable foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA, MHRA, EMA or other comparable foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

To date, we have not completed any clinical trials required for the approval of any product candidate. We may experience delays in conducting any clinical trials and we do not know whether our clinical trials we decide to conduct will begin on time, need to be redesigned, recruit and enroll patients on time or be completed on schedule, or at all. Clinical trials can be delayed, suspended or terminated for a variety of reasons, including in connection with:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation of clinical trials;
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical trials;
- delays in developing suitable assays for screening patients for eligibility for trials with respect to certain product candidates;

- delays in reaching agreement with the FDA, MHRA, EMA or other regulatory authorities as to the design or implementation of our clinical trials;
- obtaining regulatory authorization to commence a clinical trial;
- reaching an agreement on acceptable terms with clinical trial sites or prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- obtaining institutional review board, or IRB, approval at each trial site;
- recruiting suitable patients to participate in a clinical trial;
- having patients complete a clinical trial or return for post-treatment follow-up;
- inspections of clinical trial sites or operations by applicable regulatory authorities, or the imposition of a clinical hold;
- clinical sites, CROs or other third parties deviating from trial protocol or dropping out of a trial;
- failure to perform in accordance with the applicable regulatory requirements, including FDA's GCP requirements, or applicable regulatory requirements in other countries;
- addressing patient safety concerns that arise during the course of a trial, including occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- adding a sufficient number of clinical trial sites;
- manufacturing sufficient quantities of product candidate for use in clinical trials; or
- suspensions or terminations by IRBs of the institutions at which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities due to a number of factors, including those described above.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize any product candidates or significantly increase the cost of such trials, including:

- we may experience changes in regulatory requirements or guidance, or receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors and collaborators may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we or our collaborators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate and we may not have funds to cover the costs;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;

- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- any future collaborators that conduct clinical trials may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of product candidates we may seek to develop beyond those that we plan for, if we are unable to successfully complete clinical trials of such product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- incur unplanned costs;
- be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings or Risk Evaluation and Mitigation Strategies, or REMS;
- be subject to additional post-marketing testing requirements;
- be subject to changes in the way the product is administered; or
- have regulatory authorities withdraw or suspend their approval of the product or impose restrictions on its distribution after obtaining marketing approval.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the DSMB for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Any product candidate we may seek to develop will require extensive clinical testing before we are prepared to submit an NDA, BLA or marketing authorization application, or MAA, for regulatory approval. We cannot predict with any certainty if or when we might complete the clinical development for any product candidates we may seek to develop and submit an NDA, BLA or MAA for regulatory approval of any such product candidates or whether any such NDA, BLA or MAA will be approved. We may also seek feedback from the FDA, or other regulatory authorities on our clinical development program, and such regulatory authorities may not provide such feedback on a timely basis, or such feedback may not be favorable, which could further delay our development programs.

We cannot predict with any certainty whether or when we might complete a given clinical trial. If we experience delays in the commencement or completion of clinical trials for any product candidates we may seek to develop, or if we terminate a clinical trial prior to completion, the commercial prospects of any such product candidates could be harmed, and our ability to generate revenues from such product candidates may be delayed or lost. In addition, any delays in our clinical trials could increase our costs, slow down the development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and results of operations. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

The regulatory approval processes of the FDA, MHRA, EMA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain required regulatory approval for product candidates we may seek to develop, our business will be substantially harmed.

The time required to obtain approval or other marketing authorizations by the FDA, MHRA, EMA and comparable foreign authorities is unpredictable, and it typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, and the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate, and it is possible that we may never obtain regulatory approval for any product candidates we may seek to develop in the future. Neither we nor any future collaborator is permitted to market any drug product candidates in the United States until we receive regulatory approval of an NDA or BLA from the FDA, and we cannot market them in the European Union until we receive approval for a MAA from the EMA, or in other foreign countries until we receive the required regulatory approval in such other countries.

Prior to obtaining approval to commercialize any drug product candidate in the United States or abroad, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA, MHRA, EMA or other comparable foreign regulatory agencies, that such product candidates are safe, pure and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA, MHRA, EMA or other regulatory agency may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or after approval, or it may object to elements of our clinical development programs.

Any product candidates we may seek to develop could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our or any future collaborators' clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of products in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval and marketing authorization process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval and marketing authorization to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

If we are successful in licensing or otherwise acquiring new product candidates, our business will be dependent on our ability to successfully complete preclinical and clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize such product candidates in a timely manner.

Even if we eventually complete clinical testing and receive approval of an NDA or BLA or foreign marketing application for any product candidates, the FDA, MHRA, EMA or the applicable foreign regulatory agency may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-marketing clinical trials. The FDA, MHRA, EMA or the applicable foreign regulatory agency also may approve or authorize for marketing a product candidate for a more limited indication or patient population than we originally request, and the FDA, MHRA, EMA or applicable foreign regulatory agency may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

In addition, the FDA, MHRA, EMA and other regulatory authorities may change their policies, issue additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials. Any product candidates we may seek to develop may not have favorable results in later clinical trials, if any, or receive regulatory approval.

Success in preclinical testing and early stage clinical trials, including testing and trials conducted by us or any future collaborator does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Preclinical tests and Phase 1 and Phase 2 clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in preclinical or animal studies and early clinical trials does not ensure that later large-scale efficacy trials will be successful nor does it predict final results. For example, we may be unable to identify suitable animal disease models for any product candidates we may seek to develop, which could delay or frustrate our ability to proceed into clinical trials or obtain marketing approval. Product candidates we may seek to develop may fail to show the desired safety and efficacy in clinical development despite having progressed through preclinical studies and initial clinical trials.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

Interim, "top-line" and preliminary results from clinical trials that we may announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

If we are successful in licensing or otherwise acquiring new product candidates, from time to time we may publish interim, top-line or preliminary results from our clinical trials. Interim results from clinical trials that we may announce are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary, top-line or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we and they may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated.

Further, others, including regulatory agencies may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular development program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed meaningful by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, product candidates may be materially harmed, which could significantly harm our business prospects.

Any preclinical studies and clinical trials of product candidates we may seek to develop may fail to demonstrate substantial evidence of the safety and efficacy of such product candidates, or serious adverse or unacceptable side effects may be identified during the development of such product candidates, which could prevent, delay or limit the scope of regulatory approval of such product candidates, limit their commercialization, increase our costs or necessitate the abandonment or limitation of the development of some or all of such product candidates.

To obtain the requisite regulatory approvals for the commercial sale of any product candidate we may seek to develop, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that such product candidates are safe, pure and potent for use in each target indication. These trials are expensive and time consuming, and their outcomes are inherently uncertain. Failures can occur at any time during the development process. Preclinical studies and clinical trials often fail to demonstrate safety or efficacy of the product candidate studied for the target indication, and most product candidates that begin clinical trials are never approved.

We may fail to demonstrate with substantial evidence from adequate and well-controlled trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that product candidates we may seek to develop are safe and potent for their intended uses.

If any product candidates we may seek to develop are associated with undesirable side effects in preclinical studies or clinical trials or have characteristics that are unexpected, we may decide or be required to perform additional preclinical studies or to halt or delay further clinical development of such product candidates or to limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for the product candidate, if approved.

If any such undesirable side effects or unexpected characteristics are observed, our clinical trials could be suspended or terminated. If we cannot demonstrate that any adverse events observed in clinical trials were not caused by the product candidate, the FDA, MHRA, EMA or comparable foreign regulatory authorities or an IRB may also require that we suspend, discontinue, or limit our clinical trials based on safety information, or that we conduct additional animal or human studies regarding the safety and efficacy of such product candidates which we have not planned or anticipated. Such findings could further result in regulatory authorities failing to provide marketing authorization for such product candidates or limiting the scope of the approved indication, if approved. Even if we are able to demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of such product candidates, 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.

Additionally, if one or more of the product candidates we may seek to develop receives marketing approval, and we or others identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may suspend, withdraw or limit approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients or other requirements subject to a REMS;
- we may be required to change the way a product is administered or conduct additional trials;
- we could be sued and held liable for harm caused to patients;
- we may decide to remove the product from the market;
- we may not be able to achieve or maintain third-party payor coverage and adequate reimbursement;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties; and
- our reputation and physician or patient acceptance of our products may suffer.

There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or comparable foreign regulatory agency in a timely manner or at all. Moreover, any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

As a company, we do not have experience completing clinical trials and may be unable to complete clinical trials for any product candidates we may develop.

We are early in our efforts to potentially license or otherwise acquire in new product candidates and will need to, among other things, successfully complete clinical trials, including pivotal clinical trials, in order to obtain FDA, MHRA, EMA or comparable foreign regulatory authorities' approval to market any such product candidates. Carrying out clinical trials and the submission of a successful NDA, BLA or MAA is a complicated process. We have no experience completing any clinical trial, have limited experience in preparing regulatory submissions and have not previously submitted an NDA, BLA or MAA for any product candidate. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to submission of the applicable regulatory applications and approval of any product candidate. We may require more time and incur greater costs than our potential competitors and may not succeed in obtaining regulatory approvals of any product candidate that we seek to develop. Failure to commence or complete, or delays in, clinical trials could prevent us from or delay us in commercializing any product candidate.

We may experience delays or difficulties in the enrollment and/or retention of patients in clinical trials, which could delay or prevent our receipt of necessary regulatory approvals.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population and competition for patients eligible for our clinical trials with competitors which may have ongoing clinical trials for product candidates that are under development to treat the same indications as one or more of the product candidates we may seek to develop, or approved products for the conditions for which we may seek to develop product candidates.

Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities. We cannot predict how successful we will be at enrolling subjects in future clinical trials. Subject enrollment is affected by other factors including:

- the severity and difficulty of diagnosing the disease under investigation;
- the eligibility and exclusion criteria for the trial in question;

- the size of the patient population and process for identifying patients;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the design of the trial protocol;
- the perceived risks and benefits of the product candidate in the trial;
- the availability of competing commercially available therapies and other competing therapeutic candidates' clinical trials for the disease or condition under investigation;
- the willingness of patients to be enrolled in our clinical trials;
- the efforts to facilitate timely enrollment in clinical trials;
- potential disruptions caused by disease outbreaks, epidemics and pandemics, including difficulties in initiating clinical sites, enrolling and retaining participants, diversion of healthcare resources away from clinical trials, travel or quarantine policies that may be implemented, and other factors;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

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 expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of any clinical trials that we conduct and we will have limited influence over their performance.

Furthermore, even if we are able to enroll a sufficient number of patients for any clinical trials which we may conduct, we may have difficulty maintaining enrollment of such patients in our clinical trials.

We may expend our limited resources to pursue a particular product candidate or indication and fail to pursue other more promising 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 management resources, we must focus on licensing, acquiring or investing in potential product candidates that we identify for specific indications within a certain price range. As a result, we may forego or delay pursuing opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable products or profitable market opportunities. Any spending on future development programs and product candidates for specific indications may not yield any commercially viable products. For example, in the second half of 2024 and throughout 2025, our strategy prioritized development of AXN-2510, which we discontinued in January 2026, and prior to that our strategy prioritized development of TIL cell therapy products. Further, 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.

If we do not achieve our plans and projected goals in the timeframes we announce, the trading price of our common stock may be negatively impacted.

From time to time, we may estimate the timing of the accomplishment of various business development, scientific, clinical, regulatory or other goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of, or availability of data from, preclinical studies and clinical trials and the submission of regulatory filings, or business development activities. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are, and will be, based on a

variety of assumptions. The actual timing of these milestones can vary significantly compared to our estimates, in some cases for reasons beyond our control. We may experience numerous unforeseen events that could delay or prevent our ability to achieve our goals and meet any projected milestones. In addition, failure to meet projected milestones may negatively impact the trading price of our common stock and our ability to raise additional capital on attractive terms or at all.

Risks Related to the Manufacturing of Product Candidates

Therapeutic product candidates can be complex and difficult to manufacture. We intend to rely on third parties to produce clinical supply of any product candidate we may seek to develop and commercial supplies of any approved product. This reliance on third parties increases the risk that we will not have sufficient quantities of product candidates or any approved products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We expect to rely on third parties to manufacture and to perform quality testing for any product candidate we may license or otherwise acquire and seek to develop. Reliance on third parties exposes us to risks associated with having minimal control over manufacturing activities, and any disruptions to the operations of our third-party manufacturers, including those caused by conditions unrelated to our business or operations such as bankruptcy of the manufacturer, could materially and adversely affect our business.

We do not operate manufacturing facilities for the production of clinical or commercial supplies of any product candidates and currently have no supply agreements for the production of any product candidates. We have no personnel with expertise in manufacturing product candidates and lack the resources and the capabilities to manufacture product candidates on any scale, including clinical or commercial scale. We currently plan to rely on third parties for supply of product candidates we may license or otherwise acquire and seek to develop and for commercial supply if any of such product candidates are approved for sale.

If we seek to develop any product candidate, we will need to secure supply agreements with third-party manufacturers for development, validation and manufacturing of such products candidates. We may be unable to secure agreements for clinical or commercial supply with third-party manufacturers, or may be unable to do so on acceptable terms. The third-party manufacturers may not successfully carry out their contractual duties or obligations, the occurrence of which could substantially increase our costs and limit our supply of such product candidates. The demand for third-party manufacturer's services is very high, and such manufacturers could be subject to market transactions including mergers, acquisitions and other market consolidation transactions that limit their ability to provide products and services to us thereby increasing the time and cost it could take us to manufacture our product candidates or any approved products.

Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers, entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible diversion of manufacturing capacity to other customers by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or non-renewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers, may not be able to comply with current cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, 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.

Any product candidates and products that we may develop may compete with other product candidates and products 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. In addition, in order to conduct late-stage clinical trials of any product candidates we may seek to develop, we will need to have them manufactured in large quantities. Third-party manufacturers that we engage, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all.

Moreover, if third-party manufacturers that we engage are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of that product candidate may be delayed or not obtained, which could significantly harm our business.

If the third parties that we engage to manufacture product for any preclinical tests and/or clinical trials that we may seek to conduct should cease to continue to do so for any reason, we likely would experience delays in advancing these clinical trials while we identify and qualify replacement suppliers, and we may be unable to obtain replacement supplies on terms that are favorable to us. In addition, if we are not able to obtain adequate supplies of product candidates we may seek to develop or the drug substances used to manufacture them, it will be more difficult for us to develop such product candidates and compete effectively.

If third-party manufacturers for any product candidate we seek to develop divert their capacity and/or supply of materials needed for such product candidates, our ability to complete clinical trials or eventually bring product candidates to market may be compromised.

We expect to rely on third party manufacturers for any product candidates we may develop.

Our expected reliance on third party manufacturers will expose us to the risk that such manufacturers may divert their capacity and/or supply of materials needed for any product candidates we may seek to develop, compromising our ability to complete clinical trials or commercialize such product candidates. Large pharmaceutical companies with greater resources, either through acquisitions, market consolidation or otherwise, may be able to obtain privileged access to manufacturing capacity and/or supply of material needed for the manufacture of such product candidates. If our competitors are able to use their resources to secure preferential access to the supply capacity of third party manufacturers, or if third party manufacturers elect to terminate their contracts with us in favor of exclusive contracts with other larger pharmaceutical companies, our ability to obtain a supply of any product candidates we may seek to develop may be impacted resulting in significant delays and higher costs for development and commercialization of such product candidates

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and product characteristics. Such changes carry the risk that they will not achieve our intended objectives. Any such changes could cause product candidates we seek to develop to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue. In addition, we may be required to make significant changes to our upstream and downstream processes across our pipeline, which could delay the development of our future product candidates.

Risks Related to the Commercialization of Product Candidates

Even if any product candidates we may seek to develop receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any product candidates we may seek to develop receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If such product candidates do not achieve an adequate level of acceptance, we may not generate significant revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy, safety and potential advantages compared to alternative treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- product labeling or product insert requirements of the FDA, MHRA, EMA or other comparable foreign regulatory authorities, including any limitations or warnings contained in a product's approved labeling, including any black box warning or REMS;
- the willingness of the target patient population to try new treatments and of physicians to prescribe these treatments;
- our ability to hire and retain a sales force;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement for our product candidates, once approved;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

If we are unable to establish sales, marketing and distribution capabilities for any product candidate that may receive regulatory approval, we may not be successful in commercializing those product candidates if and when they are approved.

We do not have sales or marketing infrastructure. To achieve commercial success for any product candidate for which we may obtain marketing approval, we will need to establish a sales and marketing organization. In the future, we may seek to build a focused sales and marketing infrastructure to market product candidates in the United States, if 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. This 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 market our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians in order to educate physicians about our product candidates, once approved;
- 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 are forced to enter into arrangements with, and rely on, third parties to perform these services, our revenue and our profitability, if any, are likely to be lower than if we had developed such capabilities ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable 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 our product candidates.

The treatable populations for any product candidates we may seek to develop may be smaller than we or third parties currently project, which may affect the addressable markets for such product candidates.

Any projections of the number of people who have the diseases we may seek to treat, as well as the subset of people with these diseases who have the potential to benefit from treatment with product candidates we may seek to develop, will be estimates based on our knowledge and understanding of these diseases. These estimates may prove to be incorrect and new studies may report lower incidence or prevalence estimates of these diseases. The number of patients in the United States, the European Union and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with our product candidates or patients may become increasingly difficult to identify and access, all of which would adversely affect our business, financial condition, results of operations and prospects. Further, even if we obtain approval for any product candidates we seek to develop, the FDA or other regulators may limit their approved indications to more narrow uses or subpopulations within the populations for which we are targeting development of our product candidates.

The total addressable market opportunity for any product candidates we may seek to develop will ultimately depend upon a number of factors including the diagnosis and treatment criteria included in the final label, if approved for sale in specified indications, acceptance by the medical community, patient access and product pricing and reimbursement. Incidence and prevalence estimates are frequently based on information and assumptions that are not exact and may not be appropriate, and the methodology is forward-looking and speculative. The process we have used in developing an estimated incidence and prevalence range for the indications we are targeting has involved collating limited data from multiple sources. Accordingly, any incidence and prevalence estimates included in our filings with the Securities and Exchange Commission, or the SEC, or otherwise should be viewed with caution. Further, the data and statistical information used in our filings with the SEC and other presentations, including estimates derived from them, may differ from information and estimates made by our competitors or from current or future studies conducted by independent sources.

Off-label use or misuse of any products we may seek to develop may harm our reputation in the marketplace, result in injuries that lead to costly product liability suits, and/or subject us to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with any product.

If any product candidates that we may seek to develop are approved by the FDA, we may only promote or market our product candidates for their specifically approved indications. We will train our marketing and sales force against promoting our product candidates for uses outside of the approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our products off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. Furthermore, the use of our products for indications other than those approved by the FDA may not effectively treat such conditions. Any such off-label use of our product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our products for these uses for which they are not approved, which could lead to product liability suits that that might require significant financial and management resources and that could harm our reputation.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the U.S. Federal Trade Commission, the Department of Justice, or the DOJ, the Office of

Inspector General of the U.S. Department of Health and Human Services, or HHS, state attorneys general, members of the U.S. Congress, and the public. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign entities and stakeholders. Violations, including actual or alleged promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries, and investigations, and civil and criminal sanctions by the FDA, DOJ, or comparable foreign bodies. Any actual or alleged failure to comply with labeling and promotion requirements may result in fines, warning letters, mandates to corrective information to healthcare practitioners, injunctions, or civil or criminal penalties.

We face significant potential competition from other biotechnology and pharmaceutical companies, and from non-profit institutions, which may result in others identifying, discovering, developing or commercializing products before or more successfully than we do.

Drug development is highly competitive and subject to rapid and significant technological advancements. There are many large and small pharmaceutical companies focused on identifying, developing and delivering therapeutics in indications we might target. Further, it is likely that additional drugs will become available in the future for the treatment of any indications we may seek to target.

Universities and public and private research institutions in the United States and Europe are also potential competitors. While these universities and public and private research institutions primarily have educational objectives, they may develop proprietary technologies that lead to FDA-approved therapies or secure patent protection that could compete with or we may need for the development of future technologies and product candidates.

Many of our potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the United States and in foreign countries. Our potential future competitors may also have significantly more experience commercializing drugs. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small number of our potential competitors.

We will face competition from other drugs or from other non-drug products currently approved or that will be approved in the future, including for the treatment of diseases and disorders in the therapeutic categories we may seek to target. Therefore, our ability to compete successfully will depend largely on our ability to:

- develop and commercialize drugs that are superior to other products in the market;
- demonstrate through clinical trials that product candidates that we may seek to develop are differentiated from existing and future therapies;
- attract qualified scientific, product development and commercial personnel;
- obtain patent or other proprietary protection for our medicines;
- obtain required regulatory approvals;
- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors; and
- successfully collaborate with pharmaceutical companies and/or non-profit institutions in the discovery, development and commercialization of new medicines.

The availability of competitors' products could limit the demand, and the price we are able to charge, for any product candidate we seek to develop. The inability to compete with existing or subsequently introduced drugs would have an adverse impact on our business, financial condition and prospects.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make any product candidates we seek to develop less

competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our potential competitors may succeed in obtaining patent protection, discovering, developing, receiving regulatory and marketing approval for, or commercializing, drugs before we do, which would have an adverse impact on our business and results of operations.

The success of any product candidates we seek to develop will depend significantly on coverage and adequate reimbursement or the willingness of patients to pay for these therapies.

We believe our success depends on obtaining and maintaining coverage and adequate reimbursement for the product candidates we may seek to develop and the extent to which patients will be willing to pay out-of-pocket for such products, in the absence of reimbursement for all or part of the cost. In the United States and in other countries, patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. The availability of coverage and adequacy of reimbursement for our products by third-party payors, including government health care programs (e.g., Medicare, Medicaid, TRICARE), managed care providers, private health insurers, health maintenance organizations, and other organizations is essential for most patients to be able to afford medical services and pharmaceutical products. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a payor-by-payor basis. One payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage, and adequate reimbursement. The principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within HHS. CMS decides whether and to what extent products will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree.

Third-party payors determine which products and procedures they will cover and establish reimbursement levels. Even if a third-party payor covers a particular product or procedure, the resulting reimbursement payment rates may not be adequate. Patients who are treated in-office for a medical condition generally rely on third-party payors to reimburse all or part of the costs associated with the procedure, including costs associated with products used during the procedure, and may be unwilling to undergo such procedures in the absence of such coverage and adequate reimbursement. Physicians may be unlikely to offer procedures for such treatment if they are not covered by insurance and may be unlikely to purchase and use our product candidates, if approved, for our stated indications unless coverage is provided and reimbursement is adequate. In addition, for products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs.

Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that a procedure is safe, effective and medically necessary; appropriate for the specific patient; cost-effective; supported by peer-reviewed medical journals; included in clinical practice guidelines; and neither cosmetic, experimental, nor investigational. Further, increasing efforts by third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or comparable regulatory approvals. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. For example, the U.S. Department of Health and Human Services, or HHS, imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. HHS has also been empowered to negotiate the price of certain single-source biologics that have been on the market for at least eleven (11) years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. Additionally, we may also need to provide discounts to purchasers, private health plans or government healthcare programs. Our product candidates may nonetheless not be considered medically necessary or cost-effective.

If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. We expect to experience pricing pressures from third-party payors in connection with the potential sale of any of our product candidates. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales. Further, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained for one or more of our product candidates, if approved, less favorable coverage policies and reimbursement rates may be implemented in the future.

Foreign governments also have their own healthcare reimbursement systems, which vary significantly by country and region, and we cannot be sure that coverage and adequate reimbursement will be made available with respect to the treatments in which our products are used under any foreign reimbursement system.

There can be no assurance that any product candidates we seek to develop, if approved for sale in the United States or in other countries, will be considered medically reasonable and necessary, that it will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available or that reimbursement policies and practices in the United States and in foreign countries where our products are sold will not adversely affect our ability to sell our product candidates profitably, if they are approved for sale.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of any product candidates we may seek to develop in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or drugs caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

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

Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we could incur. We may need to increase our insurance coverage depending on the clinical development plans of any product candidates we may seek to develop or if we commence commercialization of any such 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.

Risks Related to Our Dependence on Third Parties

We intend to rely on third parties to conduct, supervise and monitor a significant portion of our research and preclinical testing and clinical trials for any product candidates we may seek to develop, and if those third parties do not successfully carry out their contractual duties, comply with regulatory requirements or otherwise perform satisfactorily, we may not be able to obtain regulatory approval or commercialize product candidates, or such approval or commercialization may be delayed, and our business may be substantially harmed.

We do not have a pre-clinical research or clinical operations team and intend to engage CROs and other third parties to conduct any preclinical studies and clinical trials and to monitor and manage data for any product candidates we may seek to develop. We intend to rely on third parties, including clinical data management organizations, medical institutions and clinical investigators, to conduct any clinical trials we may conduct. We may not be able to timely enter into arrangements with third parties or to do so on commercially reasonable terms, if at all. Though we intend to carefully manage our relationships with any CROs we engage, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. Further, the performance of our CROs and other third parties conducting any trials we may conduct may also be interrupted by public health emergencies.

In addition, any third parties conducting future clinical trials on our behalf 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 these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize any product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

We intend to rely on these parties for execution of any preclinical studies and clinical trials, and generally will not control their 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 responsibilities. For example, we will remain responsible for ensuring that each clinical trial we conduct is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials we conduct to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. If we or any of our CROs or other third parties, including trial sites, fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, MHRA, 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 clinical trial we may conduct will comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP conditions. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Furthermore, these third parties may also have relationships with other entities, some of which may be our potential competitors. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be delayed in obtaining regulatory approvals for any product candidates we may seek to develop and may be delayed in our efforts to successfully commercialize such product candidates for targeted diseases.

We also are required to register certain ongoing clinical trials and post the results of certain 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.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA 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 and may ultimately lead to the denial of marketing approval our product candidates.

We also expect to rely on other third parties to store and distribute product supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our

product candidates or commercialization of our products, producing additional losses and depriving us of potential revenue.

We may seek collaborations with third parties for the development or commercialization of any product candidates we may seek to develop. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We may seek third-party collaborators for the development and commercialization of any product candidates we may seek to develop. Our likely collaborators for any such arrangements include regional and national pharmaceutical companies and biotechnology companies. If we enter into any additional 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 our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates would pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a 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 our product candidates 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;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or drugs, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If any future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for any 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, MHRA, 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 for our product candidate. 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 such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate revenue.

Risks Related to our Intellectual Property

If we or our future licensors are unable to obtain and maintain sufficient patent protection for any product candidates we may seek to develop, or if the scope of the patent protection is not sufficiently broad, third parties, including our potential competitors, could develop and commercialize products similar or identical to ours, and our ability to commercialize our product candidates may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to any product candidates we may seek to develop.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. We cannot offer any assurances about which of, any our future patent applications will issue, the breadth of any resulting patent or whether any of the issued patents will be found invalid and unenforceable or will be threatened by third parties. We cannot offer any assurances that the breadth of our resulting or granted patents will be sufficient to stop a competitor from developing and commercializing a product, including a biosimilar product, that would be competitive with one or more of our product candidates. There is no assurance that all the potentially relevant prior art relating to our patent and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we or our future licensors were the first to file any patent application related to our product candidates and

technologies. Additionally, a derivation proceeding before the United States Patent and Trademark Office can be initiated by a third party to contest inventorship of the subject matter claimed in our applications.

Furthermore, any successful challenge to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any of our product candidates and technologies that we may develop. Even if they are unchallenged or such third-party challenges are unsuccessful, our patent and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates and technologies, or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent and patent applications we hold, obtain or pursue with respect to our product candidates and technologies is challenged, or if they fail to provide meaningful exclusivity for our product candidates and technologies, it could threaten our ability to commercialize our product candidates and technologies. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection, if approved, would be reduced.

The patent prosecution process is expensive and time-consuming. We may not be able to prepare, file and prosecute all necessary or desirable patent applications at a commercially reasonable cost, in a timely manner, or in all jurisdictions. It is also possible that we may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection. Moreover, depending on the terms of any future in-licenses to which we may become a party, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology in-licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. In addition to the protection provided by our patent estate, we rely on trade secret protection and confidentiality agreements to protect proprietary scientific, business and technical information and know-how that is not or may not be patentable or that we elect not to patent. We seek to protect our proprietary information, data and processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and partners. Although these agreements are designed to protect our proprietary information, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Although we generally require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed with all third parties who may have helped to develop our intellectual property or who had access to our proprietary information, or that our agreements will not be breached. If any of the parties to these confidentiality agreements breaches or violates the terms of such agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result.

Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming, and the outcome is unpredictable. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. We cannot guarantee that our employees, former employees or consultants will not file patent applications claiming our inventions. Because of the "first-to-file" laws in the United States and the uncertainties surrounding outcomes of derivation proceedings before the United States Patent and Trademark Office, such unauthorized patent application filings may defeat our attempts to obtain patents on our own inventions.

Trade secrets and know-how can be difficult to protect as trade secrets and know-how will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could purchase our products 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 protected technology or develop their own technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets and proprietary know-how were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

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. 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.

While we have confidence in these individuals, organizations and systems, our agreements or security measures may be breached, and we may not have adequate remedies for any breach. Also, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Patent terms may be inadequate to protect our competitive position on any product we may seek to develop for an adequate amount of time, and if we do not obtain protection under the Hatch-Waxman Amendments and similar non-United States legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering product candidates we may seek to develop are obtained, once the patent life has expired for a product, we may be open to competition from generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates may expire before or shortly after such candidates are commercialized. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and 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 drug, a method for using it, or a method for manufacturing it may be extended. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced and could have a material adverse effect on our business.

If we fail to comply with our obligations imposed by any intellectual property licenses with third parties that we may need in the future, we could lose rights that are important to our business.

We may in the future require licenses to additional third-party technology and materials. Such licenses may not be available in the future or may not be available on commercially reasonable terms, or at all, which could have a material adverse effect on our business and financial condition. Even if we acquire the right to control the prosecution, maintenance and enforcement of the licensed and sublicensed intellectual property relating to our product candidates, we may require the cooperation of our licensors and any upstream licensor, which may not be

forthcoming. Therefore, we cannot be certain that the prosecution, maintenance and enforcement of these patent rights will be in a manner consistent with the best interests of our business. If we or any future licensor fail to maintain such patents, or if we or our licensor lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated and our right to develop and commercialize any of our product candidates that are the subject of such licensed rights could be adversely affected. In addition to the foregoing, the risks associated with patent rights that we license from third parties will also apply to patent rights we may own in the future. Further, if we fail to comply with our development obligations under our license agreements, we may lose our patent rights with respect to such agreement, which would affect our patent rights worldwide.

Termination of any future license agreements would reduce or eliminate our rights under these agreements and may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. Any of the foregoing could prevent us from commercializing our other product candidates, which could have a material adverse effect on our operating results and overall financial condition.

In addition, intellectual property rights that we in-license in the future may be sublicenses under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to develop and commercialize our product candidates may be materially harmed.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future patents.

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States. Furthermore, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific, and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act included a number of significant changes to U.S. patent law. These included provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO has developed new and untested regulations and procedures to govern the full implementation of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, became effective in March 2013. The Leahy-Smith Act has also introduced procedures making it easier for third parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. Finally, the Leahy-Smith Act contained new statutory provisions that require the USPTO to issue new regulations for their implementation, and it may take the courts years to interpret the provisions of the new statute. It is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, 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 future patents. Further, the United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the United States Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have owned or licensed or that we might obtain in the future. An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Similarly, changes in patent laws and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we may obtain in the future. As an example, some European patent applications will have the option, upon grant of a patent, of becoming a Unitary Patent, which will be subject to the jurisdiction of the Unified Patent Court, or UPC. The option of a Unitary Patent is a significant change in European patent practice. As the UPC is a new court system, there is limited precedent for the court, increasing the uncertainty of any litigation in the UPC. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance in a given country of a patent covering an invention is not followed by the issuance in other countries of patents covering the same invention, or if any judicial interpretation of the validity, enforceability or scope of the claims or the written description or enablement, in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

We may be involved in lawsuits to protect or enforce patents protecting product candidates we may seek to develop, which could be expensive, time consuming and unsuccessful.

Potential competitors may infringe issued patents or any patents issued as a result of pending or future patent applications related to product candidates we may seek to develop. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party in such infringement proceeding from using the technology at issue on the grounds that our or our licensor's patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of such patents at risk of being invalidated, held unenforceable or interpreted narrowly, and could put any of our patent applications at risk of not yielding an issued patent.

If we initiate legal proceedings against a third party to enforce a patent covering a product candidate we may seek to develop, the defendant could counterclaim that the patent covering our product or product candidate is invalid and/or unenforceable. In patent litigation in the United States, counterclaims alleging invalidity and/or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the PTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, *inter partes* review and equivalent proceedings in foreign jurisdictions (for example, opposition proceedings, nullity proceedings or litigation or invalidation trials or invalidation proceedings). Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could have a material adverse impact on our business.

Derivation proceedings initiated by third parties or us may be necessary to determine the inventorship (and possibly also ownership) of inventions with respect to our patent applications or resulting patents, or patent applications or resulting patents of third parties. An unfavorable outcome could require us to cease using the related technology or force us to take a license under the patent rights of the prevailing party, if available. Furthermore, our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our

defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

We may not identify relevant third party patents or may incorrectly interpret the relevance, scope or expiration of a third party patent which might adversely affect our ability to develop and market products.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope and validity of patent claims or the expiration of relevant patents, are or will be complete or thorough, nor can we be certain that we have identified or will identify each and every third party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of product candidates we may seek to develop in any jurisdiction.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

We may be unsuccessful in licensing or acquiring intellectual property from third parties that may be required to develop and commercialize our product candidates.

A third party may hold intellectual property, including patent rights that are important or necessary to the development and commercialization of product candidates we may seek to develop. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize such product candidates, in which case we would be required to acquire or obtain a license to such intellectual property from these third parties, and we may be unable to do so on commercially reasonable terms or at all. 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 or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain.

Our commercial success depends in part on our ability to develop, manufacture, market and sell drug candidates that we may seek to develop and use our proprietary technologies without infringing or otherwise violating the patents and proprietary rights of third parties. As any future product candidate we may seek to develop progresses toward commercialization, the possibility of a patent infringement claim against us would increase. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation proceedings, post grant

reviews, inter partes reviews, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates, and there may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates and technologies. Third parties, including our competitors may initiate legal proceedings against us alleging that we are infringing or otherwise violating their patent or other intellectual property rights.

We cannot provide any assurance that any product candidates we may seek to develop will not infringe other parties' patents or other proprietary rights, and competitors or other parties may assert that we infringe their proprietary rights in any event. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and future product candidates, including interference or derivation proceedings before the USPTO. 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 have a negative impact on our ability to commercialize our product candidates. 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 high and requires 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 agree with us and invalidate the claims of any such U.S. patent. Moreover, given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future.

While we may decide to initiate proceedings to challenge the validity of these or other patents in the future, we may be unsuccessful, and courts or patent offices in the United States and abroad could uphold the validity of any such patent. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims 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 or sale of our product candidates. Regardless of when filed, we may fail to identify relevant third-party patents or patent applications, or we may incorrectly conclude that a third-party patent is invalid or not infringed by our product candidates or activities. If a patent holder believes that one of our product candidates infringes its patent, the patent holder may sue us even if we have received patent protection for our technology. In addition, third parties may obtain patents in the future and claim that our product candidates or technologies infringe upon these patents. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the drug or product candidate that is the subject of the actual or threatened suit.

If we are found to infringe a third party's valid intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we may be unable to effectively market product candidates based on our technology, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Under certain circumstances, we could be forced, including by court orders, to cease commercializing our product candidates. In addition, in any such proceeding or litigation, we could be found liable for substantial monetary damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed the patent at issue. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business.

The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management's attention.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biotechnology or biopharmaceutical companies. 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 we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our future patents. 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 personnel. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

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

We may also be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patent applications, our future patents issued as a result of our pending or future applications, or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing product candidates we may seek to develop. Although 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, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we 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, valuable intellectual property. Such an outcome could have a material adverse effect on our business. 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.

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

If we rely on third parties to manufacture or commercialize any product candidates we may seek to develop, or if we collaborate with additional third parties for the development of such product candidates, we must, at times, share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing 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, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of

our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, 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. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. 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, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

We may enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing and prosecuting patent applications and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive. Potential competitors may use our technologies in jurisdictions where we do not obtain patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as that in the United States or Europe. These products may compete with the product candidates we may seek to develop, and our future patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications before they are granted. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may even be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

While we intend to protect any intellectual property rights in any product candidates we may seek to develop in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and Europe and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property rights, especially those relating to life sciences, which could make it difficult for us to stop the infringement of our future patents or marketing of competing products in violation of our proprietary rights generally. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our future patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing as patents, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. 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 from third parties.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our future 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. The following examples are illustrative:

- others may be able to make products that are similar to or otherwise competitive with product candidates we may seek to develop but that are not covered by the claims of our or future collaborator's current or future patents;
- an in-license necessary for the manufacture, use, sale, offer for sale or importation of one or more product candidates we may seek to develop may be terminated by the licensor;
- we or future collaborators might not have been the first to make the inventions covered by our licensed-in, issued or future issued patents or our pending patent applications;
- we or future collaborators might not have been the first to file patent applications covering certain of our inventions or the inventions we have licensed-in;
- others may independently develop similar or alternative technologies or duplicate any technologies we may seek to develop without infringing our intellectual property rights;
- it is possible that our future pending patent applications will not lead to issued patents;
- issued patents that we own or in-license may be held invalid or unenforceable as a result of legal challenges by our competitors;
- issued patents that we own or in-license may not provide coverage for all aspects of our product candidates in all countries;
- our potential competitors might conduct research and development activities in countries where we do not have patent 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; and
- the patents of others may have an adverse effect on our business.

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

Risks Related to Legal and Regulatory Compliance Matters

Our relationships with customers, healthcare providers, including physicians, and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, including physicians, and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations promulgated under such laws. These laws will impact, among other things, our clinical research, proposed sales, marketing and educational programs, and other interactions with healthcare professionals. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind in return for, or to induce, either the referral of an individual, or the purchase, lease, order or arrangement for or recommendation of the purchase, lease, order or arrangement for any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation;
- the federal civil and criminal false claims laws, including, without limitation, the federal False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from the federal government, including Medicare, Medicaid and other government payors, that are false or fraudulent or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. federal government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-reimbursable, uses. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes which prohibit, among other things, a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without the appropriate authorization by entities subject to the law, such as health plans, healthcare clearinghouses and healthcare providers and their respective business associates and their covered subcontractors;
- the federal transparency laws, including the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program, with specific exceptions, to report annually to CMS, information related to: (i) payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and (ii) ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations; state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; 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, or that otherwise restrict payments that may be made to healthcare providers; and state and local laws that require certain regulatory licenses to manufacture or distribute our products commercially and/or the registration of pharmaceutical sales representatives.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. 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 penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in federal and state funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, diminished profits and future earnings, reputational harm and the curtailment or restructuring of our operations, any of which could harm our business.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Even if we obtain regulatory approval for any product candidates we may seek to develop, they will remain subject to ongoing regulatory oversight, which may result in significant additional expense.

Even if we obtain any regulatory approval for any product candidates we may seek to develop, they will be subject to ongoing regulatory requirements applicable to manufacturing, labeling, packaging, storage, advertising, promoting, sampling, record-keeping and submission of safety and other post-market information, among other things. Any regulatory approvals that we receive for any product candidates may also be subject to a risk evaluation and mitigation strategy, limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or requirements that we conduct potentially costly post-marketing testing and surveillance

studies, including Phase 4 trials and surveillance to monitor the quality, safety and efficacy of the drug. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval. We will further be required to immediately report any serious and unexpected adverse events and certain quality or production problems with our products to regulatory authorities along with other periodic reports.

Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. We will also have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drug products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we will not be allowed to promote our products for indications or uses for which they do not have approval, commonly known as off-label promotion. The holder of an approved NDA or BLA must submit new or supplemental applications and obtain prior approval for certain changes to the approved product, product labeling, or manufacturing process. A company that is found to have improperly promoted off-label uses of their products may be subject to significant civil, criminal and administrative penalties.

In addition, drug manufacturers are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the NDA, BLA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a drug, such as adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that drug, a regulatory authority may impose restrictions relative to that drug, the manufacturing facility or us, including requesting a recall or requiring withdrawal of the drug from the market or suspension of manufacturing.

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

- issue a deficiency letter, untitled letter or warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending marketing application or supplement to an approved application or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;
- restrict the marketing or manufacturing of the drug;
- seize or detain the drug or otherwise require the withdrawal of the drug from the market;
- refuse to permit the import or export of products or product candidates; 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 and harm our business, financial condition, results of operations and prospects.

Even if we obtain FDA, MHRA or EMA approval for any product candidates we may seek to develop in the United States or European Union, we may never obtain approval for or commercialize any of them in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy.

Approval by the FDA in the United States or the EMA in the European Union does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in foreign markets, and we do not have experience in obtaining regulatory approval in any jurisdiction, including in foreign markets. If we fail to comply with regulatory requirements in foreign markets or to obtain and maintain required approvals, or if regulatory approvals in foreign markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we seek to develop will be unrealized.

Healthcare legislative or regulatory reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there has been significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the EU and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Since its enactment, there have been amendments and judicial, Congressional and executive branch challenges to certain aspects of the ACA. For example, on July 4, 2025, the OBBBA was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

There have been amendments to executive, judicial and congressional challenges to certain aspects of the ACA. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year, which began in 2013 and will remain in effect until 2032 unless additional Congressional action is taken.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct to consumer platform, or TrumpRx, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to

or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again, or MAHA, Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager, or PBM, payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court's Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.We cannot predict which additional measures may be adopted or the impact of current and additional measures on the marketing, pricing and demand for our product candidates, if approved, which could have a material adverse effect on our business, financial condition and results of operations. In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for our product candidates. We cannot determine how changes in regulations, statutes, policies, or interpretations when and if issued, enacted or adopted, may affect our business in the future. Such changes could, among other things, require:

- additional clinical trials to be conducted prior to obtaining approval;
- changes to manufacturing methods;
- recalls, replacements, or discontinuance of one or more of our products; and
- additional recordkeeping.

Further, the standards that the FDA and comparable foreign regulatory authorities use require judgment and can change, which makes it difficult to predict with certainty their application. We may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or the impact of such changes, if any.

Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of our product candidates, and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any products would harm our business, financial condition, and results of operations.

If our information technology systems or those of the third parties with whom we work or our data, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

In the ordinary course of our business, we, and the third parties with whom we work, collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit and share (collectively, process) proprietary, confidential and sensitive data, including personal data (such as health-related data), data about trial participants in connection with clinical trials, intellectual property sensitive third-party data and trade secrets (collectively, sensitive information). Cyber-attacks, malicious internet-based activity, online and offline fraud and other similar activities threaten the confidentiality, integrity and availability of our sensitive information and information technology systems and those of the third parties with whom we work. Such threats are

prevalent and continue to rise, are increasingly difficult to detect and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, and the third parties with whom we work, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain and ability to produce, sell and distribute our goods and services. We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which are increasingly difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, attacks enhanced or facilitated by AI, and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

It may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems. For example, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment, or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.

We rely on third parties and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, encryption and authentication technology, employee email and other functions. We also rely on third-party service providers to provide other products, services or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If these third parties experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if these third parties fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or in the supply chains of the third parties with whom we work have not been or will not be compromised.

Certain of the previously identified or similar threats have in the past and could in the future cause a security incident or other interruption that have in the past and could in the future result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties with whom we work. For example, we have been the target of unsuccessful phishing attempts and unsuccessful attempts to impersonate key personnel in email in the past, and we expect such attempts will continue in the future. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our services. We expend significant resources and we may have to modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations require us to implement and maintain specific security measures to protect our information technology systems and sensitive information.

It may be difficult or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps to detect, mitigate and remediate vulnerabilities in our information systems (such as our hardware or software, including that of third parties with whom we work), but we have not in the past and may not in the future be able to detect and remediate all vulnerabilities, including on a timely basis. Further, we have (and may in the future) experienced delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders (including affected individuals, customers, regulators, and investors) of security incidents, or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences. If we, or a third party with whom we work, experience a security incident or are perceived to have experienced a security incident, we may experience material adverse consequences. These consequences may include government enforcement actions (for example, investigations, fines, penalties, audits and inspections), additional reporting requirements and/or oversight, restrictions on processing sensitive information (including personal data), litigation (including class claims), indemnification obligations, negative publicity, reputational harm, monetary fund diversions, interruptions in our operations (including availability of data), financial loss and other similar harms.

Some of our contracts do not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

We are subject to a variety of stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and data security, and our actual or perceived failure to comply with them could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information. Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations relating to data privacy and security.

In the United States, federal, state and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act) and other similar laws (e.g., wiretapping laws). For example, HIPAA as amended HITECH, imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information. Numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording

residents with rights concerning their personal data. For example, the California Consumer Privacy Act of 2018, or the CCPA, as amended applies to personal data of consumers, business representatives and employees who are California residents and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. The CCPA and other comprehensive U.S. state privacy laws exempt some data processed in the context of clinical trials, but these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties with whom we work. Other states have also passed or are considering comprehensive privacy laws, and similar laws are being considered at the federal and local levels. These developments may further complicate compliance efforts and may increase legal risk and compliance costs for us and the third parties with whom we work.

We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the UK GDPR and the CCPA, require our customers to impose specific contractual restrictions on their service providers. We publish privacy policies, marketing materials and other statements regarding data privacy and security. Regulators in the United States are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, misleading, unfair or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and security are quickly changing, becoming increasingly stringent and creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources. These obligations may necessitate changes to our services, information technologies, systems and practices and to those of any third parties that process personal data on our behalf. We may at times fail, or be perceived to have failed, in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties with whom we work fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar), litigation (including class-action claims) and mass arbitration demands, additional reporting requirements and/or oversight, bans on processing personal data, orders to destroy or not use personal data and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business or financial condition, including but not limited to loss of customers, interruptions or stoppages in our business operations including clinical trials, inability to process personal data or to operate in certain jurisdictions, limited ability to develop or commercialize any products, expenditure of time and resources to defend any claim or inquiry, adverse publicity or substantial changes to our business model or operations. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations.

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 costs that could seriously harm our business.

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 could involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations could 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 our current or past facilities and 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, product development and manufacturing 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, which could seriously harm our business.

Risks Related to Employee Matters and Managing our Growth

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 management, development, clinical, financial and business development expertise of our executive officers. Each of our executive officers may currently terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or employees.

Recruiting and retaining qualified 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 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 may 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, including in formulating our development and commercialization strategy for any product candidates we may seek to develop. 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. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our strategy will be limited.

Our resources may not be sufficient to manage our future growth; failure to properly manage our potential growth could disrupt our operations and adversely affect our business, financial condition, results of operations and prospects.

Even if we obtain funding for operations, we may fail to adequately manage our future growth. As and to the extent we are successful in licensing or otherwise acquiring and developing new product candidates, we expect to experience significant growth and change in the scope of our operations, particularly in the areas of clinical product development, regulatory affairs, manufacturing and, if any of our product candidates receives marketing approval, sales, marketing and distribution. Any change in our operations may place a significant strain on our administrative, financial and operational resources, and increase demands on our management, as well as our operational and administrative systems, controls and other resources. There can be no assurances that our existing personnel, systems, procedures or controls will be adequate to support our operations in the future; or that we will be able to successfully implement appropriate measures consistent with our strategy. To strategically manage our future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit, train and retain additional personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such potential future growth, we may not be able to effectively manage the strategic expansion of our operations, manage our employee base or recruit, train

and retain additional personnel. Our failure to properly manage our potential growth 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.

Our employees, independent contractors, consultants, collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, collaborators, principal investigators, CROs, suppliers and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter 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 governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such 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, including the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations.

Risks Related to Ownership of our Common Stock and our Status as a Public Company

An active trading market for our common stock may not continue to be developed or sustained.

Our common stock is listed on The Nasdaq Stock Market LLC. If an active trading market for our shares does not continue to be developed or sustained, it may be difficult for you to sell shares of our common stock at an attractive price or at all.

The trading price of the shares of our common stock has been and may continue to be very volatile, and purchasers of our common stock could incur substantial losses.

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

- our ability to license-in or otherwise acquire any new product candidates and the perceived attractiveness of any such product candidates;
- the commencement, enrollment or results of any future clinical trials we may conduct, or changes in the development status of any product candidates we may seek to develop;
- any delay in our regulatory filings for any product candidate we may seek to develop, and any adverse development or perceived adverse development with respect to the applicable regulatory

authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;

- delays in or termination of clinical trials;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- unanticipated serious safety concerns related to the use of any product candidate;
- changes in financial estimates by us or by any equity research analysts who might cover our stock;
- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- announcements by our competitors with respect to competing product candidates or new product candidates or technologies, or the results of clinical trials or regulatory decisions;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures, such as our recent strategic reprioritization and restructurings;
- our relationships with any collaborators;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- changes in the structure of healthcare payment systems;
- general political and economic conditions, including fluctuations in interest rates and tariffs; and
- other events or factors, many of which are beyond our control.

The stock market in general, and the Nasdaq Stock Market and smaller biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors, including armed conflicts, supply chain disruptions, heightened inflation and fluctuations in interest rates, tariffs, recent and potential future international trade disruptions and potentially worsening global economic or geopolitical conditions, may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this section, could have a significant and material adverse impact on the market price of our common stock.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. This risk is especially relevant for us because pharmaceutical and biotechnology companies have experienced significant stock

volatility in recent years. Recently, multiple plaintiffs' law firms publicly issued announcements stating that they are investigating potential securities law claims on behalf of our investors. Such litigation, if instituted against us, could cause us to incur substantial costs, subject us to damages or settlement awards and divert management's attention and resources from our business, which could materially harm our reputation, business, financial condition, results of operations and prospects.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that equity research analysts publish about us and our business. We have only limited research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

A significant portion of our total outstanding shares are available for immediate resale. This 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 could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly.

In addition, we have filed registration statements on Form S-8 under the Securities Act of 1933, as amended, or the Securities Act, registering the issuance of approximately 2.0 million shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements on Form S-8 will be available for sale in the public market subject to vesting arrangements and exercise of options.

If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other stockholders. For example, our Board of Directors has the authority to issue up to 10,000,000 shares of preferred stock. The Board of Directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents also contain other provisions that could have an anti-takeover effect, including:

- only one of our three classes of directors will be elected each year;
- stockholders will not be entitled to remove directors other than by a 66 2/3% vote and only for cause;
- stockholders will not be permitted to take actions by written consent;

- stockholders cannot call a special meeting of stockholders; and
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Our executive officers, directors and current beneficial owners of 5% or more of our common stock and their respective affiliates beneficially own a significant portion of our outstanding common stock. As a result, these persons, acting together, would be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets, or other significant corporate transactions.

Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the current market price of our common stock and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

We are an "emerging growth company" and a "smaller reporting company" and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies and smaller reporting companies, our common stock may be less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- not being required to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (i) December 31, 2026, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion, (iii) the last day of the fiscal year in which we are deemed to be a "large

accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may, under certain circumstances, still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

We will have broad discretion in the use of our cash and cash equivalents.

We have broad discretion over the use of our cash and cash equivalents. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. Our failure to apply our cash and cash equivalents effectively could compromise our ability to pursue our strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. You will not have the opportunity to influence our decisions on how to use our cash and cash equivalents.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.

You should not rely on an investment in our common stock to provide dividend income. We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our common stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the 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 breach of fiduciary duty;
- any action asserting a claim against us arising under the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of 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 amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action 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 amended and 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 a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

General Risk Factors

We have incurred and will continue to incur increased costs and demands upon management as a result of being a public company.

As a public company listed in the United States, we incur significant additional legal, accounting and other costs. These additional costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and the Nasdaq Stock Market, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies.

We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, on committees of our Board of Directors or as members of senior management.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and the rules and regulations of the stock market on which our common stock is listed. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting.

We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in our Annual Report on Form 10-K each year, as required by Section 404 of the Sarbanes-Oxley Act. This requires that we incur substantial professional fees and internal costs on accounting and finance functions and that we expend significant management efforts.

We may identify weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the Securities and Exchange Commission or other regulatory authorities.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

We are subject to taxation in more than one tax jurisdiction. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including passage of newly enacted tax legislation or regulations, changes in the mix of our profitability from jurisdiction to jurisdiction, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities and changes in accounting for income taxes. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

We might not be able to utilize a significant portion of our net operating loss carryforwards.

We have generated and expect to continue to generate in the future significant federal and state net operating loss, or NOL, carryforwards. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. U.S. federal NOLs incurred in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOL carryforwards in a taxable year is limited to 80% of taxable income in such year. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. Our initial public offering, together with private placements and other transactions that have occurred since our inception, may have triggered such an ownership change pursuant to Section 382. We have not yet completed a Section 382 analysis. We may experience ownership changes as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our NOL carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. We have a full valuation allowance for deferred tax assets including NOLs.

Our business activities could be subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery and anti-corruption laws.

Our business activities could be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-United States government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-United States governments. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers will be subject to regulation under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of

our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer products in one or more countries as well as difficulties in manufacturing or continuing to develop products, and could materially damage our reputation, our brand, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

Disruptions at the FDA and other government agencies caused by funding shortages, layoff, shifting priorities under the new administration or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, layoffs and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition, the current administration has discussed several changes to the reach and oversight of the FDA, which could affect its relationship with the pharmaceutical industry, transparency in decision making and ultimately the cost and availability of prescription drugs. Additionally, over the last several years, the U.S. government has shut down multiple times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA and other government employees and stop critical activities. If funding for the FDA is reduced, FDA priorities change, or a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

Our business, financial condition and results of operations could be adversely affected by general conditions in the global economy, the global financial markets and global political conditions. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of ongoing military conflicts, terrorism or other geopolitical events, and political tensions between the U.S. and China. Sanctions imposed by the United States and other countries in response to such conflicts and political tensions may also adversely impact our business, the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. Furthermore, a severe or prolonged economic downturn, including a recession or depression or major epidemic or pandemic, or political disruption could result in a variety of risks to our business and could negatively impact, among other things, our ability to raise additional capital when needed on acceptable terms, if at all. Any of the foregoing could seriously harm our business, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could seriously harm our business.

Non-U.S. holders of our common stock may be subject to U.S. federal income tax if we are considered a United States real property holding corporation.

Non-U.S. holders of our common stock may be subject to U.S. federal income and/or withholding tax in the event we are considered a United States real property holding corporation, or USRPHC, for U.S. federal income tax purposes. We believe that we currently are not considered a USRPHC. However, because this determination is made from time to time and is dependent upon a number of factors, some of which are beyond our control, including the value of our assets, there can be no assurance that we will not become a USRPHC. If we ultimately are determined by the United States Internal Revenue Service to constitute a USRPHC, certain of our non-U.S. holders may be subject to U.S. federal income or withholding tax, or both, in respect of certain dispositions of our common stock.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity

Risk management and strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and clinical trial data or Information Systems and Data.

The Company's information technology (IT) Department, led by our Global Head of IT, helps identify, assess, and manage the Company's cybersecurity threats and risks. The IT Department identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example subscribing to reports and services that identify certain cybersecurity threats, analyzing reports of threats and actors, using automated tools to identify certain risks within our collaboration environment, evaluating certain threats reported to us, engaging third parties to conduct threat assessments, conducting vulnerability assessments, and using external intelligence feeds.

Depending on the environment and systems, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: incident response policy, incident detection and response, employee cybersecurity awareness training, encryption of certain data, endpoint detection and response for certain endpoints, network security controls, physical security, access controls, asset management, tracking and disposal, systems monitoring, cybersecurity insurance, and a managed Security Operations Center (SOC).

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, our senior management along with our IT Department evaluates material risks from cybersecurity threats against our overall business objectives and reports to the Audit Committee of our Board of Directors, which evaluates our overall enterprise risk.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example: a threat intelligence service provider, cybersecurity software providers, and managed cybersecurity service providers.

We use third-party service providers to perform a variety of functions throughout our business, such as application providers, hosting companies, contract research organizations, and contract manufacturing organizations. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider, including reviewing security assessment reports from certain vendors.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including "*If our information technology systems or those of the third parties with whom we work or our data, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.*" and "*We are subject to a variety of stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and data security, and our actual or perceived failure to comply with them could*

lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences."

Governance

Our Board of Directors addresses the Company's cybersecurity risk management as part of its general oversight function. The Audit Committee of our Board of Directors is responsible for overseeing Company's cybersecurity risk management processes, including oversight of mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, including our Global Head of IT who has over 20 years of experience managing cybersecurity and IT risks, including working at other biotechnology and cell therapy companies.

The Global Head of IT along with the Chief Financial Officer ("CFO") are responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy, and communicating key priorities to relevant personnel. The CFO is responsible for approving cybersecurity-related budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response policy is designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including our Global Head of IT, CFO and Chief Executive Officer ("CEO"). Our Global Head of IT, CFO and CEO work with the Company's incident response team to help the Company mitigate and remediate cybersecurity incidents of which they are notified.

The Audit Committee receives periodic reports of certain cybersecurity incidents from our Global Head of IT pursuant to the Company's incident response plan and the processes the Company has implemented to address them. The Audit Committee also has access to various reports, summaries or presentations related to cybersecurity threats, risk, and mitigation.

Item 2. Properties.

Our wholly owned subsidiary, Complex Therapeutics LLC, owns a manufacturing facility in Tarzana, California and in July 2024 it leased the facility to AstraZeneca. The facility consists of 128,097 square feet of clinical and commercial manufacturing space.

Our headquarters is located in Dallas, Texas and consists of 5,055 square feet of leased office space under a lease that expires in April 2026. We also lease 7,728 square feet of leased laboratory and office space in Alderley Park, United Kingdom, under three leases that expire in November 2026.

We believe that our current facilities are adequate for our current needs.

Item 3. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. 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 for Common Stock

Our common stock is listed on the Nasdaq Stock Market under the symbol "TIL".

Holders of our Common Stock

As of March 25, 2026, there were 13 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

Dividend Policy

We have never declared or paid, and do not anticipate declaring or paying in the foreseeable future, any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business.

Recent Sales of Unregistered Equity Securities

None.

Issuer 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 included in this Annual Report on Form 10-K. This discussion contains forward-looking statements that reflect our plans, estimates and beliefs and involve numerous risks and uncertainties, including but not limited to those described in the "Risk Factors" section of this Annual Report. Actual results may differ materially from those contained in any forward-looking statements. You should carefully read the "Special Note Regarding Forward-Looking Statements," "Risk Factor Summary," and "Risk Factors" sections above.

Overview

We are a biotechnology company focused on identifying and advancing innovative therapeutic opportunities.

In January 2026, we announced that our wholly owned subsidiary, Axion Bio, was discontinuing development of AXN-2510, our former lead product candidate. We are actively seeking to in-license or acquire and develop additional novel therapeutic candidates in diseases with significant unmet medical need.

Since inception, we have had significant operating losses. Our net loss was $71.4 million and $74.1 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $726.5 million. As of December 31, 2025, we had cash, cash equivalents, restricted cash and marketable securities of $76.3 million, which consisted of $6.6 million in cash and cash equivalents, $0.2 million of restricted cash and $69.5 million in marketable securities. We expect to continue to incur net losses for the foreseeable future.

Components of Operating Results

Operating Expenses

In-Process Research and Development

In-process research and development (IPR&D) expenses include IPR&D acquired as part of in-license payments made to ImmuneOnco for our prior product candidate AXN-2510, for which there is no alternative future use and are expensed as incurred.

Research and Development

Research and development expenses consist primarily of research and development, manufacturing, monitoring and other services payments and, to a lesser extent, salaries, benefits and other personnel-related costs, including stock-based compensation, professional service fees, and facility and other related costs. In addition, research and development expense is presented net of reimbursements from reimbursable tax and expenditure credits and grants from the UK government.

We expect our future research and development expenses to change in line with our potential business development activities and any nonclinical and clinical development activities. Our expenditures on any future nonclinical and clinical development programs are subject to numerous uncertainties in timing and cost to completion. The duration, costs and timing of clinical trials and development of product candidates will depend on a variety of factors, including:

- the scope, rate of progress and expenses of clinical trials and other research and development activities;
- potential safety monitoring and other studies requested by regulatory agencies;
- significant and changing government regulation; and
- the timing and receipt of regulatory approvals, if any.

The process of conducting the necessary clinical research to obtain regulatory approval from the FDA, Medicines and Healthcare Products Regulatory Agency, or MHRA, European Medicines Agency, or EMA, and

comparable foreign authorities is costly and time consuming and the successful development of product candidates is highly uncertain. The risks and uncertainties associated with our research and development projects are discussed more fully in the section of this Annual Report titled "Risk Factors." As a result of these risks and uncertainties, we are unable to determine with any degree of certainty the duration and completion costs of our research and development projects, or if, when or to what extent we will generate revenues from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates.

General and Administrative

General and administrative expenses consist primarily of compensation and personnel-related expenses, including stock-based compensation, for our personnel in executive, finance and other administrative functions. General and administrative expenses also include professional fees paid for accounting, auditing, legal, tax and consulting services, insurance costs, recruiting costs, travel expenses, facility and other related costs, depreciation, and other general and administrative costs.

We expect to continue to incur expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC, director and officer insurance expenses, and any investor relations related expenses, as well as other administrative and professional services.

Restructuring and Impairment Charges

Restructuring and impairment charges for the year ended December 31, 2025 consisted primarily of fees related to terminated contracts and an impairment loss recognized on long-lived assets held for sale in connection with listing the Tarzana facility for sale in March 2025.

Restructuring and impairment charges for the year ended December 31, 2024 consisted primarily of employee termination costs, contract terminations, and impairment loss recognized on long-lived assets held for sale, leasehold improvements, and right-of-use assets.

In January 2023, our Board of Directors approved a restructuring plan, or the 2023 Plan, related to the consolidation of our former ITIL-306 Phase 1 clinical trial and related manufacturing of CoStAR-TIL to our operations in Manchester, UK.

In January 2024, we decided to initiate closure of our UK manufacturing and clinical operations related to our past development of our CoStAR-TIL technology, and in September 2024 we decided to close most of our remaining Manchester, UK operations related to our past development of our CoStAR-TIL technology, which resulted in the elimination of the majority of the remaining UK workforce, with the remaining reduction substantially completed by the end of 2024, which we refer to as the 2024 Plan, and collectively with the 2023 Plan, as the Plan.

As a result of the Plan, we incurred restructuring and impairment charges of $16.6 million and $7.5 million during the years ended December 31, 2025 and 2024, respectively.

Interest Income

Interest income consists of interest income from funds held in our cash and cash equivalent accounts and marketable securities.

Interest Expense

Interest expense consists of interest expense on our debt and amortization of loan origination costs.

Other Rental Income

Other rental income consists of rental income related to the Tarzana facility.

Other Income (Expense), Net

Other income (expense), net consists primarily of derivative financial instrument fair value gain or loss, foreign exchange remeasurement gain or loss, debt extinguishment loss and other expenses and income.

Income Tax Provision

We are subject to income taxes in the United States and the United Kingdom. The United Kingdom has statutory tax rates that differ from those in the United States. Accordingly, our effective tax rates will vary depending on the relative proportion of United Kingdom to United States income, the availability of research and development tax credits, changes in the valuation of our deferred tax assets and liabilities and changes in tax laws.

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Due to the uncertainty of the business in which we operate, projections of future profitability are difficult and past profitability is not necessarily indicative of future profitability. We maintain full valuation allowance against net deferred tax assets for the United States and the United Kingdom. The valuation allowance has been provided based on the positive and negative evidence relative to our company, including the existence of cumulative net operating losses, or NOLs, since our inception, and the inability to carryback these NOLs to prior periods. Furthermore, we have determined that it is more likely than not that the benefit of these assets would not be realized in the foreseeable future. The timing and the reversal of our valuation allowance will continue to be monitored.

On July 4, 2025, the One Big Beautiful Bill Act, or OBBBA, was signed into law and included various tax policy changes. OBBBA did not have a material impact on our 2025 consolidated financial statements.

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 (in thousands):

	Year Ended December 31,		Change
	2025	2024	$
Operating expenses:			
In-process research and development	$ 10,000	$ 10,000	$ —
Research and development	24,738	11,838	12,900
General and administrative	27,221	44,210	(16,989)
Restructuring and impairment charges	16,622	7,493	9,129
Total operating expenses	78,581	73,541	5,040
Loss from operations	(78,581)	(73,541)	(5,040)
Interest income	3,858	6,987	(3,129)
Interest expense	(5,829)	(8,992)	3,163
Other rental income	8,968	4,267	4,701
Other income (expense), net	212	(2,856)	3,068
Net loss	$ (71,372)	$ (74,135)	$ 2,763

In-process Research and Development Expenses

In-process research and development expenses were $10.0 million for each of the years ended December 31, 2025 and 2024, due to a $10.0 million payment to ImmuneOnco for achievement of the IND clearance milestone during the year ended December 31, 2025 and an upfront payment to ImmuneOnco during year ended December 31, 2024.

Research and Development Expenses

Research and development expenses were $24.7 million and $11.8 million for the years ended December 31, 2025 and 2024, respectively. The net increase of $12.9 million was primarily due to:

- $17.7 million increase in costs related to research and clinical development activities from our ImmuneOnco collaboration and our AXN-2510 clinical trial; partially offset by
- $2.8 million decrease in costs from reduced headcount, consisting primarily of decreases of $2.9 million in wages and benefits, $1.3 million in stock-based compensation expense, and $0.1 million for other employee-related expenses in relation to our research and development personnel; partially offset by a $1.5 million increase in professional services; and
- $2.0 million decrease in expenses related to facilities, overhead, depreciation, and other expenses due to strategic reductions made in these areas.

The following table shows our research and development expenses by program for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
In-process research and development:		
AXN-2510/IMM2510	$ 10,000	$ 10,000
Research and development:		
AXN-2510/IMM2510	20,351	1,291
Other program expenses [1]	4,387	10,547
Total research and development by program	$ 24,738	$ 11,838
Total research and development expenses	$ 34,738	$ 21,838

(1) Other program expenses consist of costs related to our past development of our CoStAR-TIL technology.

General and Administrative Expenses

General and administrative expenses were $27.2 million and $44.2 million for the years ended December 31, 2025 and 2024, respectively. The net decrease of $17.0 million was primarily due to:

- $10.5 million decrease in costs resulting from decreases in headcount and personnel related costs, including a decrease in stock-based compensation expense of $7.3 million;
- $4.4 million decrease in depreciation, facility costs, and insurance expenses; and
- $2.1 million decrease in consulting and professional service costs, mainly consisting of decreases in costs of business operations consultants of $2.0 million and information technology and facility consultants of $0.1 million.

Restructuring and Impairment Charges

Restructuring and impairment charges were approximately $16.6 million and $7.5 million for the years ended December 31, 2025 and 2024, respectively. The net increase of approximately $9.1 million was primarily due to:

- $12.2 million increase in costs from impairments of assets held for sale, primarily related to an impairment of the Tarzana facility; and
- $0.8 million increase in costs resulting from termination of contracts; partially offset by
- $2.7 million decrease in severance payments and benefits continuation costs;
- $0.8 million decrease in costs from impairments of right-of-use assets; and
- $0.3 million decrease in costs from leasehold improvement impairments.

Interest Income, Interest Expense, Other Rental Income and Other Income (Expense), Net

Interest income, interest expense, other rental income and other income (expense), net was $7.2 million of income and $0.6 million of expense for the years ended December 31, 2025 and 2024, respectively. The increase in income of $7.8 million was primarily due to:

- $4.7 million increase in rental income related to the Tarzana facility;
- $3.2 million decrease of interest expense from our debt;
- $2.4 million decrease in other losses, including change in fair value from terminated derivative financial instruments and debt extinguishment; and
- $0.6 million increase due to gain on foreign currency transactions; partially offset by
- $3.1 million decrease of interest income related to our investments.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have not generated any revenue from product sales and we have incurred significant operating losses. We do not have any products that have achieved regulatory marketing approval and we do not expect to generate revenue from commercial sales of any product candidate for at least several years, if ever.

Prior to our initial public offering, or IPO, we funded our operations primarily through the issuance and sale of convertible preferred stock. From our inception through March 2021, prior to our IPO, we raised net cash proceeds of $380.1 million from the issuance and sale of our convertible preferred stock.

In the first quarter of 2021, we raised net proceeds of $339.0 million in our IPO pursuant to which we sold an aggregate of 920,000 shares of common stock.

In June 2022, our wholly owned subsidiaries, Complex Therapeutics Mezzanine LLC and Complex Therapeutics LLC, entered into a mortgage construction loan and mezzanine construction loan, or together, the Construction Loans, secured by Complex Therapeutics LLC's Tarzana, California land and building. Construction of the Tarzana facility was subsequently completed and in 2024 the facility was leased to AstraZeneca Pharmaceuticals LP, or Tenant. The initial principal amount of the Construction Loans was $52.1 million, with additional future principal of up to $32.9 million to fund then ongoing construction costs. During the year ended December 31, 2024, Complex Therapeutics LLC refinanced the outstanding principal amount under the Construction Loans and we treated it as an extinguishment for accounting purposes. On December 20, 2024, or the Closing Date, Complex Therapeutics LLC entered into a Term Loan Agreement and related loan documents with Midland National Life Insurance Company, or Midland, pursuant to which Midland loaned Complex Therapeutics LLC a term loan in the principal amount of $85.6 million, or the 2024 Loan, to refinance the Construction Loans secured by the Tarzana facility. Substantially all of the 2024 Loan proceeds were used to repay in full the Construction Loans. As of December 31, 2025, the outstanding principal amount under the 2024 Loan was $85.6 million and unamortized debt issuance costs were $0.8 million.

The 2024 Loan may be prepaid in whole but not in part. If the 2024 Loan is prepaid on or prior to the 12-month anniversary of the Closing Date, a prepayment fee would have been required (other than in connection with a casualty or condemnation event) to make Midland whole for the interest it would have otherwise earned on the 2024 Loan during the first 12 months of the 2024 Loan. There is no prepayment fee due if the 2024 Loan is prepaid after the 12-month anniversary of the Closing Date.

The 2024 Loan has a term of two years with a one-year extension option. The extension option is subject to certain conditions being met, including: (a) no potential default or event of default, (b) payment of a 0.35% extension fee and the costs and expenses of Midland incurred in connection with the extension, (c) replenishing of all reserve funds as reasonably determined by Midland, and (d) compliance with minimum debt yield and debt service coverage ratio requirements. The 2024 Loan bears interest at a fixed rate of 6.35% per annum, with interest-only payments during the term of the 2024 Loan and the principal balance due in full at maturity. We expect Complex Therapeutics LLC to meet all requirements necessary to exercise the extension to extend the maturity by one year to January 2028. We expect that written notice to extend the loan will be provided as early as the 2024 Loan permits, which is no sooner than one hundred twenty days from its maturity date and no later than thirty days before its maturity date.

On November 13, 2024, we filed a shelf registration statement on Form S-3 with the SEC, which the SEC declared effective on November 21, 2024. Pursuant to our shelf registration statement we may, from time to time, sell up to an aggregate of $200 million of our common stock, preferred stock, debt securities or warrants.

In March 2025, we entered into an Open Market Sale Agreement[SM], with Jefferies LLC, or Jefferies, as sales agent, under which we may offer and sell, from time to time, shares of our common stock through Jefferies, with an aggregate offering price of up to $100 million by methods deemed to be an “at the market offering,” or the ATM Program.

As of December 31, 2025, we had sold an aggregate of 185,837 shares of our common stock under the ATM Program for net proceeds of $6.6 million after deducting commissions and expenses of approximately $0.3 million. The remaining availability under the ATM Program as of December 31, 2025 was approximately $93.1 million.

As of December 31, 2025, we had cash, cash equivalents, restricted cash and marketable securities of $76.3 million, which consisted of $6.6 million in cash and cash equivalents, $0.2 million in restricted cash and $69.5 million in marketable securities. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation.

Future Funding Requirements

Based on our current operating plan, we believe our existing cash, cash equivalents, restricted cash and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements beyond 2027.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We evaluated our ability to continue as a going concern for the twelve months following the issuance of the consolidated financial statements. As disclosed and defined in Note 8, the 2024 Loan is due in January 2027, for total principal of $85.6 million which is in excess of cash, cash equivalents, and marketable securities on hand as of December 31, 2025, which we concluded is an indicator of substantial doubt about our ability to continue as a going concern.

If we are unable to refinance the 2024 Loan prior to maturity, we plan to execute our contractual right to extend the maturity of the 2024 Loan to January 2028. In addition to our plan to exercise the extension option in the 2024 Loan, we may seek to refinance or restructure the 2024 Loan including by extending its maturity date beyond the extended date, sell the building to repay the 2024 Loan, or seek additional financing in the form of equity or debt instruments. There can be no assurance that new financing or other forms of funding will be available on favorable terms or at all. We concluded that our contractual right to exercise the extension option to January 2028 is solely within our control and alleviates the conditions that raise substantial doubt about our ability to continue as a going concern.

We use our cash to fund operations, primarily to fund our business development, research and development expenditures and related personnel costs. We expect our expenses to continue to be significant as we invest in research and development activities, particularly if we in-license or acquire product candidates, advance one or more product candidates into later stages of development and conduct clinical trials, seek regulatory approvals for and commercialize any product candidates that successfully complete clinical trials, hire personnel and invest in and grow our business, expand and protect our intellectual property portfolio, and operate as a public company. Because of the numerous risks and uncertainties associated with acquiring product candidates, and the research, development and commercialization of product candidates, we are unable to estimate the exact timing and amount of our funding requirements. Our future operating expenditures will depend on many factors, including:

- the extent to which we acquire or in-license other companies' product candidates and technologies;
- the scope, rate of progress, costs and results of future clinical and preclinical development activities;
- the costs, timing and outcome of regulatory review of any product candidates, and the number of trials required for regulatory approval;
- the cost of manufacturing any product candidates, as well as any products we successfully commercialize;
- the cost of commercialization activities of any product candidates, if approved for sale, including marketing, sales and distribution costs;
- the timing, receipt and amount of sales of any product candidates, if approved;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of any such arrangements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- any product liability or other lawsuits or claims;
- the expenses needed to attract, hire and retain skilled personnel;

- our investments in our operational, financial and management information systems;
- the costs associated with operating as a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing any intellectual property portfolio we may acquire;
- costs related to the Tarzana facility; and
- any delays or issues resulting from the impact of adverse geopolitical and economic conditions.

Until we can generate substantial revenue from sales of a product candidate, if that occurs, we plan to fund our operations through equity offerings, debt financings, leasing income, or other capital sources. This may include strategic collaborations or other arrangements with third parties. Additional funds may not be available to us on acceptable terms or at all. If we raise additional funds by issuing equity or convertible debt securities, our stockholders will suffer dilution, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities receive any distribution of our corporate assets. If we raise funds through collaborations or other similar arrangements with third parties, we may have to relinquish valuable rights to technologies, future revenue streams, product candidates or research programs or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. Our ability to raise additional funds may be adversely impacted by worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from, among other things, heightened inflation, fluctuations in interest rates, military conflicts, including in Ukraine and the Middle East, tariffs and recent and potential trade wars. If we fail to obtain necessary capital when needed on acceptable terms, or at all, it could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations. See "Risk Factors."

Cash Flows

The following table sets forth the significant sources and uses of cash for the periods set forth below (in thousands):

	Years Ended December 31,	
	2025	**2024**
Net cash (used in) provided by:		
Cash used in operating activities	$ (36,619)	$ (55,696)
Cash provided by investing activities	25,476	53,974
Cash provided by financing activities	7,292	1,755
Net (decrease) increase in cash, cash equivalents, and restricted cash	$ (3,851)	$ 33

Cash Flows from Operating Activities

Cash used in operating activities for the year ended December 31, 2025 was $36.6 million, which consisted of the net loss of $71.4 million and a $0.6 million net change to our net operating assets and liabilities, partially offset by $35.4 million in non-cash charges and other adjustments to reconcile net loss to net cash used in operating activities. The net change in our operating assets and liabilities was primarily due to an increase of $3.4 million in accrued rent receivable, a decrease of $2.3 million in accrued expenses and other current liabilities, a decrease of $1.4 million in operating lease liabilities, and a decrease of $0.1 million in long-term liabilities partially offset by a decrease of $6.1 million in prepaid expenses and other current assets, a decrease of $0.4 million in other long-term assets, and an increase of $0.1 million in accounts payable. The non-cash charges primarily consisted of impairment of property, plant and equipment of $16.6 million, in-process research and development expenses of $10.0 million, stock-based compensation of $8.7 million, non-cash interest expense of $0.8 million, depreciation expense of $0.5

million, and non-cash lease expenses of $0.2 million; partially offset by a decrease in the fair value of contingent consideration of $0.9 million, and a change in foreign exchange remeasurement of $0.5 million.

Cash used in operating activities for the year ended December 31, 2024 was $55.7 million, which consisted of the net loss of $74.1 million and a $12.6 million net change to our net operating assets and liabilities, partially offset by $31.0 million in non-cash charges and other adjustments to reconcile net loss to net cash used in operating activities. The net change in our operating assets and liabilities was primarily due to a decrease of $1.9 million in accrued expenses, accrued restructuring costs, and other current liabilities, a decrease of $1.4 million in operating lease liabilities, a decrease of $0.6 million in accounts payable, an increase of $0.2 million in prepaid expenses and other current assets, an increase of $4.2 million in accrued rent receivable, and an increase of $4.4 million in other long-term assets. The non-cash charges primarily consisted of stock-based compensation of $17.3 million, in-process research and development expenses of $10.0 million, impairment of property, plant and equipment of $4.3 million, impairment of right-of-use assets of $0.8 million and depreciation expense of $3.6 million, offset by accretion on invested securities of $4.3 million and decrease in the fair value of contingent consideration $3.9 million.

Cash Flows from Investing Activities

Cash provided by investing activities for the year ended December 31, 2025 was $25.5 million, consisting primarily of $35.0 million of cash provided by marketable securities investments and $0.4 million of cash received from asset disposals, offset by $10.0 million of acquired in-process research and development.

Cash provided by investing activities for the year ended December 31, 2024 was $54.0 million, consisting primarily of $64.1 million of cash provided by marketable securities investments, $0.9 million of cash received from asset disposals and $0.6 million of cash received from termination of derivative financial instruments, offset by $10.0 million of acquired in-process research and development and $1.6 million from the renewal of our derivative financial instrument.

Cash Flows from Financing Activities

Cash provided by financing activities for the year ended December 31, 2025 was $7.3 million, which primarily consisted of net proceeds from our ATM Program of $6.6 million and net proceeds from the exercise of stock options of $0.9 million, partially offset by closing costs related to the 2024 Loan of $0.2 million.

Cash provided by financing activities for the year ended December 31, 2024 was $1.8 million, which was primarily related to net cash proceeds from the 2024 Loan of $85.6 million and proceeds from the exercise of stock options of $0.4 million, partially offset by principal repayments of our Construction Loans of $82.8 million and closing costs related to the 2024 Loan of $1.4 million.

Contractual Obligations and Commitments

As of December 31, 2025, the outstanding principal amount under the 2024 Loan was $85.6 million and unamortized debt issuance costs were $0.8 million. The 2024 Loan matures on January 10, 2027, or the scheduled maturity date, and includes a one year extension option. Notice to exercise the extension may be provided no earlier than one hundred twenty days and no later than thirty days prior to the scheduled maturity date. We expect Complex Therapeutics LLC to meet all requirements necessary to exercise the extension.

As of December 31, 2025, we had non-cancelable purchase commitments of approximately $0.2 million consisting mainly of operating commitments. Additionally, future minimum lease payments under noncancellable operating leases as of December 31, 2025 totaled $0.4 million, as discussed in Note 8 to the consolidated financial statements included elsewhere in this Annual Report.

On January 5, 2026, Axion Bio and ImmuneOnco entered into an agreement terminating the IO Collaboration Agreement. Under the termination agreement Axion Bio agreed to transfer its rights, title and interest related to AXN-2510 and AXN-27M to ImmuneOnco, and ImmuneOnco agreed to pay Axion Bio $1.8 million.

Critical Accounting Policies and Estimates

This management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of the consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in the notes to our consolidated financial statements included elsewhere in this Annual Report, we believe that the accounting policies discussed below are most critical to understanding and evaluating our historical and expected future performance.

Stock-Based Compensation

We maintain a stock-based compensation plan as a long-term incentive for employees, directors and consultants. The plan allows for the issuance of stock options, stock appreciation rights and restricted stock units.

For stock-based awards with only service conditions, we recognize stock-based compensation expense for stock-based awards on a straight-line basis over the requisite service period and account for forfeitures as they occur. For stock-based awards with performance conditions, stock-based compensation expense is not recognized until the performance condition is probable to occur. Our stock-based compensation costs are based upon the grant date fair value estimated using the Black-Scholes option pricing model. This model utilizes inputs that are highly subjective assumptions and generally require significant judgment. These assumptions include:

- Fair Value of Common Stock—Prior to our IPO in March 2021, the fair value of the shares of common stock underlying stock options had historically been determined by the Board of Directors. Because there has been no public market for the our common stock, the Board of Directors has determined fair value of the common stock at the time of grant of the option by considering a number of objective and subjective factors including important developments in our operations, contemporaneous valuations performed by an independent third party firm, sales of our convertible preferred stock, our operating results and financial performance, the conditions in the biotechnology industry and the economy in general, the stock price volatility of similar public companies and the lack of marketability of our common stock, among other factors. After our IPO in March 2021, the fair value of common stock is determined using the closing price of our common stock on the Nasdaq Stock Market.
- Expected Term—The expected term represents the period that stock-based awards are expected to be outstanding and is determined as the average of the time-to-vesting and the contractual life of the awards.
- Expected Volatility—Since we do not have sufficient trading history for our common stock, the expected volatility was estimated based on the average volatility for comparable publicly traded biotechnology companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty.
- Risk-Free Interest Rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of awards.

- Expected Dividend Yield—We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

Assets Held for Sale

We classify long-lived assets or disposal groups to be sold as held for sale in the period in which all of the following criteria are met: management, having the authority to approve the action, commits to a plan to sell the asset or disposal group; the asset or disposal group is available for immediate sale in its present condition subject only to terms that are usual and customary for sales of such assets or disposal group; the sale of the asset or disposal group is probable, and transfer of the asset or disposal group is expected to qualify for recognition as a completed sale within one year, except if events or circumstances beyond our control extend the period of time required to sell the asset or disposal group beyond one year; the asset or disposal group is being actively marketed for sale at a price that is reasonable in relation to its current fair value; and actions required to complete the plan to sell have been initiated.

We initially measure a long-lived asset or disposal group that is held for sale at the lower of its carrying value or fair value less any costs to sell. Fair value is estimated by us through evaluations of quoted market prices received for other comparable held for sale assets sold by us. Any loss resulting from this measurement is recognized in the period in which the held for sale criteria are met. Conversely, gains are not recognized on the sale of a long-lived asset or disposal group until the date of sale. We assess the fair value of a long-lived asset or disposal group less any costs to sell each reporting period it remains classified as held for sale and report any subsequent changes as an adjustment to the carrying value of the asset or disposal group, as long as the new carrying value does not exceed the carrying value of the asset at the time it was initially classified as held for sale. Upon determining that a long-lived asset or disposal group meets the criteria to be classified as held for sale, we cease depreciation and report long-lived assets in the line item “assets held for sale” in the consolidated balance sheets.

During the year ended December 31, 2025, we determined there were indicators of impairment on the Tarzana facility listed as held for sale. As a result, we performed recoverability tests on the asset group and concluded the asset's fair value less cost to sell was less than the carrying amount. We estimate the fair value of our building through a combination of income-based and market-based approach. The income-based approach is dependent on specific assumptions such as market rental rates, capitalization rates and discount rates. The market-based approach utilizes observable data, such as comparable building sales and occupancy rates. The costs to sell were determined by estimated legal, tax, and real estate broker fees. The fair value less cost to sell of our building was determined to be $112.1 million, compared to the carrying value of $128.7 million at the time of held for sale classification. This led to an impairment of approximately $16.6 million recognized in the consolidated statements of operations and comprehensive loss in the line item “restructuring and impairment charges.” The fair value of these assets are classified within Level 2 of the fair value hierarchy.

During the year ended December 31, 2024, we recorded non-cash impairment charges for assets held for sale related to impairment of our Manchester, United Kingdom manufacturing equipment of $4.3 million recognized in the consolidated statements of operations and comprehensive loss in the line item “restructuring and impairment charges.”

Refer to Notes 2 and 13 to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Impairment of Long-Lived Assets

We review our long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable or that the useful life is shorter than originally estimated. Recoverability of assets is measured by comparing the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset over its remaining useful life. If such assets are impaired, the impairment recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. If the useful life is shorter than originally estimated, we depreciate or amortize the remaining carrying value over the revised shorter useful life. Assets to be disposed of by sale are reflected at the lower of their carrying

amount or fair value less cost to sell. To date, we have recorded impairment losses on long-lived assets associated with a sustained decrease in our stock price and our prior strategic prioritization of our preclinical and clinical development programs. We recognized a non-cash impairment charge related to leasehold improvements of nil and $0.3 million during 2025 and 2024, respectively. The impairment charges were recorded in the consolidated statements of operations and comprehensive loss in the line item "restructuring and impairment charges."

As discussed above, during the year ended December 31, 2025 we recorded impairment of approximately $16.6 million on the Tarzana facility recognized in the consolidated statements of operations and comprehensive loss in the line item "restructuring and impairment charges."

During the year ended December 31, 2024, we recorded non-cash impairment charges for assets held for sale related to impairment of our Manchester, United Kingdom manufacturing equipment of $4.3 million recognized in the consolidated statements of operations and comprehensive loss in the line item "restructuring and impairment charges."

See Notes 2 and 13 to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for more information.

Recent Accounting Pronouncements

Information regarding recent accounting pronouncements applicable to us is included in Note 2 to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Emerging Growth Company Status and Smaller Reporting Company Status

We are an "emerging growth company" as defined in the JOBS Act. For so long as we remain an emerging growth company, we are permitted and intend to rely on certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

In addition, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to avail ourselves of this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest of (i) December 31, 2026, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion, (iii) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

We are also a "smaller reporting company," as defined in Rule 12b-2 under the Exchange Act. We may continue to be a smaller reporting company if either (i) the market value of our shares held by non-affiliates is less than $250.0 million or (ii) our annual revenue was less than $100.0 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than $700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller

reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Item 10 of Regulation S-K and are not required to provide the information otherwise required under this item.

Item 8. Financial Statements and Supplementary Data.

INSTIL BIO, INC.

Index to financial statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Instil Bio, Inc.:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Instil Bio, Inc. and subsidiaries (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the two 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 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

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 Public Company Accounting Oversight Board (United States) (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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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.

/s/ Deloitte & Touche LLP

San Diego, California
March 27, 2026

We have served as the Company's auditor since 2020.

INSTIL BIO, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)

	December 31,	
	2025	**2024**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,638	$ 8,805
Restricted cash	166	1,830
Marketable securities	69,491	104,510
Prepaid expenses and other current assets	3,038	9,325
Assets held for sale	112,096	—
Total current assets	191,429	124,470
Property, plant and equipment, net	126	129,406
Operating lease right-of-use assets	238	934
Accrued rent receivable	7,664	4,267
Other long-term assets	4,066	4,490
Total assets	$ 203,523	$ 263,567
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 779	$ 659
Accrued expenses and other current liabilities	4,064	7,237
Total current liabilities	4,843	7,896
Contingent consideration	—	948
Operating lease liabilities, non-current	—	1,017
Loan payable	84,806	84,187
Other long-term liabilities	8	83
Total liabilities	89,657	94,131
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, par value $0.000001 per share; 10,000,000 shares authorized; zero shares issued and outstanding as of December 31, 2025, and 2024	—	—
Common stock, par value $0.000001 per share; 300,000,000 shares authorized; 6,781,976 and 6,525,887 shares issued and outstanding as of December 31, 2025, and 2024	—	—
Additional paid-in capital	840,937	824,780
Accumulated other comprehensive loss	(583)	(228)
Accumulated deficit	(726,488)	(655,116)
Total stockholders' equity	113,866	169,436
Total liabilities and stockholders' equity	$ 203,523	$ 263,567

The accompanying notes are an integral part of these consolidated financial statements.

INSTIL BIO, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2025	**2024**
Operating expenses:		
In-process research and development	$ 10,000	$ 10,000
Research and development	24,738	11,838
General and administrative	27,221	44,210
Restructuring and impairment charges	16,622	7,493
Total operating expenses	78,581	73,541
Loss from operations	(78,581)	(73,541)
Interest income	3,858	6,987
Interest expense	(5,829)	(8,992)
Other rental income	8,968	4,267
Other income (expense), net	212	(2,856)
Net loss	(71,372)	(74,135)
Other comprehensive income:		
Foreign currency translation	(342)	168
Unrealized loss on available-for-sale securities, net	(13)	(48)
Net comprehensive loss	$ (71,727)	$ (74,015)
Net loss per share, basic and diluted	$ (10.70)	$ (11.39)
Weighted-average shares used in computing net loss per share, basic and diluted	6,668,268	6,510,138

The accompanying notes are an integral part of these consolidated financial statements.

INSTIL BIO, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance—December 31, 2023	6,503,913	$ —	$ 807,158	$ (348)	$ (580,981)	$ 225,829
Issuance of common stock upon exercise of stock options	21,974	—	365	—	—	365
Stock-based compensation	—	—	17,257	—	—	17,257
Net loss	—	—	—	—	(74,135)	(74,135)
Other comprehensive income	—	—	—	120	—	120
Balance—December 31, 2024	6,525,887	—	824,780	(228)	(655,116)	169,436
Issuance of common stock upon exercise of stock options	70,252	—	853	—	—	853
Issuance of common stock in at-the-market offering, net of $0.3 million in issuance costs	185,837	—	6,611	—	—	6,611
Stock-based compensation	—	—	8,693	—	—	8,693
Net loss	—	—	—	—	(71,372)	(71,372)
Other comprehensive loss	—	—	—	(355)	—	(355)
Balance—December 31, 2025	6,781,976	$ —	$ 840,937	$ (583)	$ (726,488)	$ 113,866

The accompanying notes are an integral part of these consolidated financial statements.

INSTIL BIO, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (71,372)	$ (74,135)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	8,693	17,257
Non-cash lease expense	286	212
Foreign exchange remeasurement (gain) loss	(484)	275
Impairment of property, plant and equipment	16,569	4,325
Impairment of right-of-use assets	—	827
Change in fair value of contingent consideration	(948)	(3,910)
Depreciation	534	3,610
Restructuring costs	(91)	—
In-process research and development expenses	10,000	10,000
Accretion on invested securities	(37)	(4,327)
Non-cash interest expense	791	962
Non-cash loss on debt extinguishment	—	415
Change in fair value of derivative financial instrument	—	1,055
Loss on disposals of property and equipment	—	343
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	6,115	(221)
Other long-term assets	425	(4,363)
Accrued rent receivable	(3,397)	(4,267)
Accounts payable	116	(556)
Operating lease liabilities	(1,393)	(1,377)
Long-term liabilities	(79)	77
Accrued expenses and other current liabilities	(2,347)	(1,898)
Net cash used in operating activities	(36,619)	(55,696)
Cash flows from investing activities:		
Purchase of marketable securities	(100,856)	(134,009)
Maturities of marketable securities	135,900	198,100
Cash received from asset disposals	432	866
Acquired in-process research and development	(10,000)	(10,000)
Cash received from termination of derivative financial instrument	—	605
Purchase of derivative financial instrument	—	(1,588)
Net cash provided by investing activities	25,476	53,974
Cash flows from financing activities:		
Proceeds from the 2024 Loan	—	85,600
Principal payments on Construction Loans	—	(82,838)
Proceeds from at-the-market offering, net of $0.3 million in issuance costs	6,611	—
Proceeds from exercise of stock options	853	365
2024 Loan agreement closing costs	(172)	(1,372)
Net cash provided by financing activities	7,292	1,755
Net (decrease) increase in cash, cash equivalents, and restricted cash	(3,851)	33
Effect of exchange rate changes on cash, cash equivalents and restricted cash	20	(94)
Cash, cash equivalents and restricted cash—beginning of period	10,635	10,696
Cash, cash equivalents and restricted cash—end of period	$ 6,804	$ 10,635
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 5,038	$ 7,997

The accompanying notes are an integral part of these consolidated financial statements.

INSTIL BIO, INC.

Notes to Consolidated Financial Statements

1. Organization and Description of Business

Instil Bio, Inc. (the "Company") is a biotechnology company focused on identifying and advancing innovative therapeutic opportunities.

In January 2026, the Company announced that its wholly owned subsidiary, Axion Bio, Inc. ("Axion Bio"), was discontinuing development of AXN-2510/IMM2510, its former lead product candidate.

The Company is actively seeking to in-license or acquire and develop additional novel therapeutic candidates in diseases with significant unmet medical need.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of expenses during the reporting period. Significant estimates and assumptions made in the accompanying consolidated financial statements include but are not limited to the fair value of assets held for sale and determination of fair value of the Company's building, and stock-based compensation. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could differ from those estimates.

Concentration of Credit Risk

Financial Instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents, restricted cash, and marketable securities. The Company's cash and cash equivalents are held by two financial institutions in the United States ("U.S.") and one financial institution in the United Kingdom ("UK"), which management believes to be financially sound, and accordingly, minimal credit risk exists with respect to the financial institutions. At times, the Company's deposits held in the U.S. and UK may exceed the Federal Depository Insurance Corporation and Financial Services Compensation Scheme, respectively, insured limits. During the years ended December 31, 2025 and 2024, the Company has not experienced any credit losses in such accounts or marketable securities.

Risks and Uncertainties

The Company is subject to a number of risks similar to other development-stage biopharmaceutical companies, including but not limited to, the Company's ability to acquire or in-license promising product candidates, dependency on the clinical and commercial success of such product candidates, if any, ability to obtain regulatory approval of any product candidates, uncertainty of broad adoption of its approved products, if any, by physicians and patients, manufacturing, the need to obtain adequate additional funding, significant competition, and protection of its intellectual property portfolio.

Segments

Operating segments are identified as components of an entity for which separate discrete financial information is available and that is regularly reviewed by the chief operating decision maker, the Company's Chief Executive Officer, in deciding how to allocate resources to an individual segment and in assessing performance. The Company has determined it operates in a single operating segment and has one operating segment. See Note 3 for further information.

Cash, Cash Equivalents, Restricted Cash, and Marketable Securities

The Company considers all highly liquid investments purchased with original maturities of three months or less from the purchase date to be cash equivalents. Cash equivalents include amounts invested in money market accounts.

Restricted cash consists of a cash reserve which served as collateral for the Company's Construction Loans (as defined in Note 8) during the year ended December 31, 2024. As of December 31, 2025, restricted cash consists of a cash reserve allocated to future tax payments. There was $0.2 million and $1.8 million restricted cash as of December 31, 2025 and 2024, respectively, on the consolidated balance sheets.

The Company's investments in marketable securities have been classified and accounted for as available-for-sale. The Company classifies its maturities as either short-term or long-term based on each instrument's underlying contractual maturity date, which are carried at their fair values based on the quoted market prices of the securities. Unrealized gains and losses are reported as accumulated other comprehensive income (loss). Realized gains and losses on available-for-sale securities are included in net loss in the period earned or incurred. As of December 31, 2025 and 2024, marketable securities consisted of U.S. Treasury bills.

The Company periodically reviews whether its securities may be other-than-temporarily impaired, including whether or not (i) the Company has the intent to sell the security or (ii) it is more likely than not that the Company will be required to sell the security before its anticipated recovery. If one of these factors is met, the Company will record an impairment loss associated with its impaired investment. The impairment loss will be recorded as a write-down of investments in the consolidated balance sheets and a realized loss within other expense in the consolidated statements of operations and comprehensive loss. For the years ended December 31, 2025 and 2024, there were no impairment losses for the investments.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets that sum to the amounts shown in the consolidated statements of cash flows (in thousands):

	December 31,	
	2025	**2024**
Cash and cash equivalents	$ 6,638	$ 8,805
Restricted cash	166	1,830
Cash, cash equivalents and restricted cash	$ 6,804	$ 10,635

Going Concern

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Management evaluated the Company's ability to continue as a going concern for the twelve months following the issuance of the consolidated financial statements. As disclosed and defined in Note 8, the 2024 Loan is due in January 2027, for total principal of $85.6 million which is in excess of cash, cash equivalents, and marketable securities on hand as of December 31, 2025, which management has concluded is an indicator of substantial doubt about the Company's ability to continue as a going concern.

If the Company is unable to refinance the 2024 Loan prior to maturity, the Company plans to execute its contractual right to extend the maturity of the 2024 Loan to January 2028. In addition to the Company's plan to exercise the extension option in the 2024 Loan, the Company may seek to refinance or restructure the 2024 Loan including by extending its maturity date beyond the extended date, sell the building to repay the 2024 Loan, or seek additional financing in the form of equity or debt instruments. There can be no assurance that new financing or other forms of funding will be available on favorable terms or at all. Management concluded that the Company's contractual right to exercise the extension option to January 2028 is solely within the Company's control and alleviates the conditions that raise substantial doubt about the Company's ability to continue as a going concern.

Fair Value Measurement

Assets and liabilities recorded at fair value on a recurring basis in the consolidated balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability 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 maximize the use of observable inputs and minimize the use of unobservable inputs. The Company measures fair value based on a three-tier hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value as follows:

Level 1 —Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2 —Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the assets or liabilities. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3 —Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

In determining fair value, the Company utilize quoted market prices, or valuation techniques that maximize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

Property, Plant and Equipment, Net

Property, plant and equipment, with the exception of land, is stated at cost less accumulated depreciation. Depreciation is computed on a straight-line basis over the estimated useful lives of the related assets. Maintenance and repairs are charged to operations as incurred. Upon sale or retirement of assets, the cost and related accumulated depreciation are removed from the consolidated balance sheets and the resulting gain or loss is reflected in the consolidated statements of operations and comprehensive loss. The estimated useful lives of the Company's property, plant and equipment are as follows:

Computer equipment	3 years
Office furniture	7 years
Building	35 years

The Company owns land and building and, as described in Note 4, the clinical and commercial manufacturing building has been completed and has been leased. See Note 8 for details. In March 2025, the Company's board of directors (the "Board of Directors") approved a plan to sell the Tarzana facility. The Company engaged a broker to facilitate the sale of the Tarzana facility and therefore reclassified the land and building as held for sale in the consolidated balance sheet as of December 31, 2025. Refer to Note 4.

Assets Held for Sale

The Company classifies long-lived assets or disposal groups to be sold as held for sale in the period in which all of the following criteria are met: management, having the authority to approve the action, commits to a plan to sell the asset or disposal group; the asset or disposal group is available for immediate sale in its present condition subject only to terms that are usual and customary for sales of such assets or disposal group; the sale of the asset or disposal group is probable, and transfer of the asset or disposal group is expected to qualify for recognition as a completed sale within one year, except if events or circumstances beyond the Company's control extend the period of time required to sell the asset or disposal group beyond one year; and actions required to complete the plan to sell have been initiated.

The Company initially measures a long-lived asset or disposal group that is held for sale at the lower of its carrying value or fair value less any costs to sell. Fair value is estimated by the Company through evaluations of quoted market prices received for other comparable held for sale assets sold by the Company. Any loss resulting from this measurement is recognized in the period in which the held for sale criteria are met. Conversely, gains are not recognized on the sale of a long-lived asset or disposal group until the date of sale. The Company assesses the fair value of a long-lived asset or disposal group less any costs to sell each reporting period it remains classified as held for sale and reports any subsequent changes as an adjustment to the carrying value of the asset or disposal group, as long as the new carrying value does not exceed the carrying value of the asset at the time it was initially classified as held for sale. Upon determining that a long-lived asset or disposal group meets the criteria to be classified as held for sale, the Company ceases depreciation and reports long-lived assets in the line item "assets held for sale" in its consolidated balance sheets.

In March 2025, the Company's Board of Directors approved a plan to sell the Tarzana facility. The Company engaged a broker to facilitate the sale of the Tarzana facility and therefore reclassified the land and building as held for sale in the consolidated balance sheet as of December 31, 2025. The Tarzana facility is currently leased to AstraZeneca Pharmaceuticals LP ("Tenant") and Tenant has a right of first offer to purchase it. Refer to Note 8. During the year ended December 31, 2025, the Company recorded a building impairment related to the Tarzana facility of $16.6 million. During the year ended December 31, 2024, the Company recorded non-cash impairment charges for assets held for sale related to impairment of the Company's Manchester, United Kingdom manufacturing equipment of $4.3 million recognized in the consolidated statements of operations and comprehensive loss in the line item "restructuring and impairment charges." See Note 4 for more information.

Impairment of Long-Lived Assets

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable or that the useful life is shorter than originally estimated. Recoverability of assets is measured by comparing the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset over its remaining useful life. If such assets are impaired, the impairment recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. If the useful life is shorter than originally estimated, the Company depreciates or amortizes the remaining carrying value over the revised shorter useful life. During the year ended December 31, 2025 the Company recognized an impairment of long-lived assets held for sale related to the Tarzana facility of $16.6 million. During the year ended December 31, 2024, the Company recorded non-cash impairment charges for assets held for sale related to impairment of the Company's Manchester, United Kingdom manufacturing equipment of $4.3 million.

The Company recognized non-cash impairment charges of nil and $0.3 million for the years ended December 31, 2025 and 2024, respectively, related to impairment of leasehold improvements.

These non-cash impairment charges were recorded in the consolidated statements of operations and comprehensive loss in the line item "restructuring and impairment charges." See Note 13 for more information.

Research and Development Expenses

Research and development costs are expensed as incurred. Clinical trial and other development costs incurred by third parties are expensed as the contracted work is performed. The Company accrues for costs incurred as the services are being provided by monitoring the status of the trial or project and the invoices received from its external service providers. The Company adjusts its accrual as actual costs become known. Where contingent milestone payments are due to third parties under research and development arrangements or license agreements, the milestone payment obligations are expensed when the milestone results are achieved.

Stock-Based Compensation

The Company measures its stock-based awards granted to employees, non-employee directors, consultants and independent advisors based on the estimated grant date fair value of the awards. For stock-based awards with only service conditions, compensation expense is recognized over the requisite service period using the straight-line method. For stock-based awards that include performance conditions, compensation expense is not recognized until the performance condition is probable to occur. The Company uses the Black-Scholes option pricing model to estimate the fair value of its stock-based awards. The Black-Scholes option pricing model requires the Company to make assumptions and judgements about the variables used in the calculations, including the fair value of common stock, expected term, expected volatility of the Company's common stock, risk-free interest rate and expected dividend yield. The Company accounts for forfeitures of stock-based awards as they occur.

Income Taxes

Income taxes are accounted for using the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts or existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using the enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period of enactment. The Company records a valuation allowance to reduce deferred tax assets to an amount expected to be realized.

The Company recognizes the tax benefit from an uncertain tax position if it is more likely than not that the tax position will be sustained upon examination by the tax authorities, based on the merits of the position. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense or benefit. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

Foreign Currency

The Company's reporting currency is the U.S. dollar. The functional currency of the Company's subsidiary located in the United Kingdom is the British pound sterling. Balance sheets prepared in the functional currency are translated to the reporting currency at exchange rates in effect at the end of the accounting period, except for stockholders' deficit accounts, which are translated at rates in effect when these balances were originally recorded. Revenue and expense accounts are translated using an average exchange rate in effect during the period. The resulting foreign currency translation adjustments are recorded as a separate component of accumulated other comprehensive loss in the accompanying consolidated balance sheets.

Gains and losses resulting from exchange rate changes on intercompany transactions denominated in a currency other than the local currency are included in earnings as incurred as the related amounts are expected to be repaid in the foreseeable future.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of the Company's common stock outstanding for the period, without consideration for potential dilutive shares of common stock. For purposes of the diluted net loss per share calculation, convertible preferred stock and common stock

options are considered to be potentially dilutive securities. Diluted net loss per share is the same as basic net loss per share for each period presented since the effects of potentially dilutive securities are antidilutive given the net loss of the Company.

Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. For the years ended December 31, 2025 and 2024, comprehensive loss consists of foreign currency translation adjustments and unrealized loss on available-for-sale securities net of tax.

Leases

The Company determines if an arrangement is or contains a lease at contract inception by assessing whether the arrangement contains an identified asset and whether the lessee has the right to control such asset. Lessees are required to classify leases as either finance or operating leases and to record a right-of-use ("ROU") asset and a lease liability for all leases with a term greater than 12 months regardless of the lease classification. The lease classification will determine whether the lease expense is recognized based on an effective interest rate method or on a straight-line basis over the term of the lease. The Company determines the initial classification and measurement of its ROU assets and lease liabilities at the lease commencement date and thereafter if modified. For leases with a term greater than 12 months, the Company records the lease liability at the present value of lease payments over the term. The term of the Company's leases equals the non-cancellable period of the lease, including any rent-free periods provided by the lessor, and also includes options to extend or terminate the lease that the Company is reasonably certain to exercise. The ROU asset equals the carrying amount of the related lease liability, adjusted for any lease payments made prior to lease commencement, any deferred rent upon adoption, and lease incentives provided by the lessor.

The Company has elected, for all classes of underlying assets, not to recognize ROU assets and lease liabilities for leases with a term of 12 months or less. Lease cost for short-term leases is recognized on a straight-line basis over the lease term. The Company estimates its incremental borrowing rate based on the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment.

Variable lease payments are expensed as incurred and do not factor into the measurement of the applicable ROU asset or lease liability. Lease payments may be fixed or variable; however, only fixed payments are included in the Company's lease liability calculation. Lease costs for the Company's operating leases are recognized on a straight-line basis within operating expenses over the lease term. The Company's lease agreements may contain non-lease components such as common area maintenance, operating expenses or other costs, which are expensed as incurred for all classes of assets. The Company's leases do not contain any residual value guarantees. See Note 8 for further information below.

Recent Accounting Pronouncements Adopted

In December 2023, the FASB issued ASU 2023-09 "Income Taxes (Topics 740): Improvements to Income Tax Disclosures" to expand the disclosure requirements for income taxes, specifically related to the rate reconciliation and income taxes paid. ASU 2023-09 is effective for annual periods beginning after December 15, 2025, with early adoption permitted. The Company adopted ASU 2023-09 for the year ended December 31, 2025, and applied the new disclosure requirements prospectively. The adoption of this standard did not have a material impact on the Company's consolidated financial statements and disclosures. For additional information, see Note 12.

Recent Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU no. 2024-03, Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40). The amendments in this update require disclosure, in the notes to the consolidated financial statements, of specific expense categories present within expense captions presented on the face of the income statement within continuing operations of public business entities. The

amendments in this update are effective for annual periods beginning after December 15, 2026 and interim periods beginning after December 15, 2027. The Company is currently evaluating the impact of this ASU 2024-03 on its consolidated financial statements and related disclosures.

In September 2025, the FASB issued ASU No. 2025-07, Derivatives and Hedging and Revenue from Contracts with Customers - Derivatives Scope Refinements and Scope Clarification for Share-Based Noncash Consideration from a Customer in a Revenue Contract ("ASC 2025-07") which applies to all entities that enter into non-exchange-traded contracts with underlyings based on operations or activities specific to one of the parties to the contract. The new guidance excludes from derivative accounting non-exchange-traded contracts with underlyings that are based on operations or activities specific to one of the parties to the contract. ASU 2025-07 is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods within those annual reporting periods. Early adoption is permitted. The Company does not expect adoption of ASU 2025-07 to have a material impact on its consolidated financial statements and related disclosures.

A variety of proposed or otherwise potential accounting standards are currently being studied by standard-setting organizations and certain regulatory agencies. Because of the tentative and preliminary nature of such proposed standards, the Company has not yet determined the effect, if any, that the implementation of such proposed standards would have on the Company's consolidated financial statements.

3. Segment Reporting

The Company manages its business activities on a consolidated basis and has one reportable segment relating to the research and development of its novel therapies. The Chief Executive Officer, who serves as the Company's chief operating decision maker ("CODM"), is responsible for the overall supervision, direction, and management of the business and its officers.

The CODM reviews net loss, as reported in the consolidated statements of operations and comprehensive loss, as well as the progress of the Company's program(s). The CODM does not review assets in evaluating the results of the segment, and therefore, such information is not presented. All long-lived assets owned by the Company are located the United States. The accounting policies of the segment are the same as those described in Note 2.

The following table is a summary of the segment loss, including significant segment expenses for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
In-process research and development	$ 10,000	$ 10,000
AXN-2510/IMM2510	20,351	1,291
Other program expenses[1] [2]	4,387	9,901
General and administrative[1]	26,687	41,246
Restructuring charges	16,622	7,493
Depreciation	534	3,610
Interest income	(3,858)	(6,987)
Interest expense	5,829	8,992
Other income, net	(9,180)	(1,411)
Segment net loss	$ 71,372	$ 74,135

(1) Depreciation expense is removed from both "General and administrative" and "Other program expense" and is disclosed separately.

(2) Other program expenses consist of costs related to the Company's past development of its CoStAR-TIL technology.

4. Balance Sheet Components

Prepaid and other current assets

Prepaid and other current assets consisted of the following (in thousands):

	December 31,	
	2025	2024
Prepaid general and administrative	$ 1,170	$ 1,316
Prepaid research and development	441	4,146
Tax-related receivable	848	2,622
Prepaid contract research organization expenses	431	282
Other current assets	148	959
Total prepaid and other current assets	$ 3,038	$ 9,325

Property, Plant and Equipment, Net

Property, plant and equipment, net consisted of the following (in thousands):

	December 31,	
	2025	2024
Land	$ —	$ 31,243
Building	—	102,433
Office furniture and computer equipment	509	509
Total property, plant and equipment, gross	509	134,185
Less: accumulated depreciation	(383)	(4,779)
Total property, plant and equipment, net	$ 126	$ 129,406

Depreciation expense was $0.5 million and $3.6 million for the years ended December 31, 2025 and 2024, respectively, in the consolidated statements of operations and comprehensive loss.

As of December 31, 2025, the Company had $112.1 million in assets related to the Tarzana facility on the consolidated balance sheet meeting the criteria of held for sale assets. These assets are recognized at the lower of cost or fair value less costs to sell. The Company estimates the fair value of the Tarzana facility through a combination of an income-based approach and a market-based approach. The income-based approach is dependent on specific assumptions such as market rental rates, capitalization rates and discount rates. The market-based approach utilizes observable data such as comparable building sales. The fair value of these assets are classified as Level 3 in the fair value hierarchy due to a mix of unobservable inputs utilized such as proprietary independent research in the market as well as actual quotes from market participants. The Company recognized impairment of $16.6 million and nil related to the Tarzana facility during the years ended December 31, 2025 and 2024, respectively.

The Company recognized non-cash impairment charges of nil and $4.3 million related to United Kingdom equipment impairments during the years ended December 31, 2025 and 2024, respectively.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31,	
	2025	2024
Accrued compensation and benefits	$ 2,517	$ 2,691
Accrued operational expenses	43	582
Accrued restructuring costs	155	2,073
Accrued research, development and clinical trial expenses	977	209
Operating lease liabilities, current	372	1,682
Total accrued expenses and other current liabilities	$ 4,064	$ 7,237

5. Fair Value Measurement

The fair value of cash and cash equivalents approximates carrying value since cash and cash equivalents consist of short-term highly liquid investments with maturities of less than three months at the time of purchase. Cash and cash equivalents are valued based upon quoted market prices in active markets for identical assets and are therefore classified as Level 1 assets. Money market funds are open-end mutual funds that invest in cash, government securities, and/or repurchase agreements that are collateralized fully. To the extent that these funds are valued based upon the reported net asset value, they are categorized in Level 1 of the fair value hierarchy.

Short-term marketable securities consisted of U.S. Treasury bills that are classified within Level 2 of the fair value hierarchy are valued based on other observable inputs, including broker or dealer quotations, alternative pricing sources or U.S. Government Treasury yield of appropriate term.

The following tables provide information by level for assets and liabilities that are measured at fair value on a recurring and nonrecurring basis:

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Financial Assets				
Money market funds	$ 4,339	$ —	$ —	$ 4,339
U.S. Treasury bills	—	69,491	—	69,491
Total	$ 4,339	$ 69,491	$ —	$ 73,830

	December 31, 2024			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Financial Assets				
Money market funds	$ 5,632	$ —	$ —	$ 5,632
U.S. Treasury bills	—	104,510	—	104,510
Total	$ 5,632	$ 104,510	$ —	$ 110,142
Financial Liabilities				
Contingent consideration	$ —	$ —	$ 948	$ 948

There were no transfers in or out of Level 1, 2 and 3 measurements for the years ended December 31, 2025 and 2024. As of December 31, 2025 and 2024, there were no securities within Level 3 of the fair value hierarchy. As of December 31, 2024, the contingent consideration was within Level 3 of the fair value hierarchy.

As of December 31, 2025 and 2024, the fair value of the 2024 Loan (as defined in Note 8) was $85.5 million and $84.7 million, respectively. The fair value was determined on the basis of its net present value and is considered Level 2 in the fair value hierarchy.

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial liabilities (in thousands):

	Level 3 Financial Liabilities
Fair value, beginning balance as of December 31, 2023	$ 4,858
Change in fair value	(3,910)
Fair value, ending balance as of December 31, 2024	948
Change in fair value	(948)
Fair value, ending balance as of December 31, 2025	$ —

The Company's acquisition of Immetacyte involved the potential for the payment of future contingent consideration upon the achievement of (i) certain product development milestones including, approval of studies and commencement and completion of certain product trials, or (ii) various other performance conditions including, receipt of final approval for the first marketing authorization and first commercial sale in certain geographical markets. Contingent consideration is recorded at the estimated fair value of the contingent payments on the acquisition date. The fair value of the contingent consideration is remeasured at the estimated fair value at each reporting period with the change in fair value recognized as income or expense within research and development expense in the consolidated statements of operations and comprehensive loss.

During the year of acquisition, the Company determined the fair value of the contingent consideration by probability weighting scenarios of milestone achievements to determine the expected future contingent consideration payment, discounted to present value using an 8% discount rate based on the Company's pre-tax cost of debt on the acquisition date. The probability of payments was 0% and 5% as of December 31, 2025 and 2024, respectively. Determinations of the likelihood of milestone achievements, which trigger payouts related to the contingent consideration, as well as the probabilities for various scenarios used in the Company's calculations, were based on internal unobservable projections.

During the years ended December 31, 2025 and 2024, the change in fair value related to the contingent consideration was due to the discontinuation of the ITIL-306-202 development program, the change in present value for the passage of time, as well as expected dates and probabilities of milestone achievement revisions.

6. Financial Instruments

Marketable securities classified as available-for-sale on December 31, 2025 and 2024 consisted of the following (in thousands):

		December 31, 2025			
	Maturity	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury bills	Less than one year	$ 69,439	$ 58	$ (6)	$ 69,491

		December 31, 2024			
	Maturity	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury bills	Less than one year	$ 104,445	$ 99	$ (34)	$ 104,510

As of December 31, 2025 and 2024, marketable securities that had contractual maturities less than one year are classified as current because management considers these marketable securities to be available for current operations. The Company does not intend to sell its marketable securities and it is not likely that the Company will be required to sell these securities before recovery of their amortized cost basis. There were $69.5 million and $104.5 million of marketable securities classified as available-for-sale as of December 31, 2025 and December 31, 2024, respectively.

7. License and Collaboration Agreement with ImmuneOnco

On August 1, 2024, Axion Bio entered into the license and collaboration agreement with ImmuneOnco (the "IO Collaboration Agreement"). As part of this agreement, Axion Bio made a $10.0 million upfront payment to ImmuneOnco during the year ended December 31, 2024. This amount was fully expensed as in-process research and development (IPR&D) in the same year.

During the year ended December 31, 2024, Axion Bio made a $5.0 million prepayment to ImmuneOnco for development costs, which was fully expensed in research and development as of March 31, 2025. A second $5.0 million prepayment for development costs was made to ImmuneOnco in April 2025, which was fully expensed in research and development as of September 30, 2025. A third $5.0 million prepayment to ImmuneOnco for development costs was made in August 2025. This amount was partially expensed under research and development, with a remaining prepaid balance of $0.3 million recorded as of December 31, 2025.

In June 2025, Axion Bio achieved Investigational New Drug (IND) clearance in the United States for a Phase 1 trial of AXN-2510 in relapsed/refractory solid tumors. This milestone triggered a $10.0 million development payment to ImmuneOnco, which was paid in July 2025. This amount was fully expensed as IPR&D during the second quarter of 2025.

The expenses recognized in connection with the IO Collaboration Agreement were $23.8 million and $10.0 million for the year ended December 31, 2025 and 2024, respectively, and were recorded as a component of research and development expense on the consolidated statements of operations and comprehensive loss. As of December 31, 2025, no additional milestones had been accrued as the underlying contingencies had not yet been resolved.

Under the IO Collaboration Agreement, ImmuneOnco was eligible to receive additional potential near-term payments of up to $15.0 million, up to $2.1 billion in commercial, development and regulatory milestones (including up to $270.0 million in longer term development and regulatory milestones and up to $1.8 billion in commercial milestones) plus single-digit to low double-digit percentage royalties on global net sales of the licensed products outside of Greater China. On January 5, 2026, Axion Bio and ImmuneOnco entered into an agreement terminating the IO Collaboration Agreement. Under the termination agreement, Axion Bio agreed to transfer the rights, title, and interest related to AXN-2510 and AXN-27M to ImmuneOnco, and ImmuneOnco agreed to pay Axion Bio $1.8 million.

8. Commitments and Contingencies

Leases

Company as a Lessee: Operating Lease Obligations

The Company currently leases office spaces and laboratory spaces located in Dallas, Texas and Alderley Park in the United Kingdom. During April 2025, the Company terminated its prior lease in Thousand Oaks, California. The Company's leased facilities have original lease terms ranging from 2 to 5 years that in general require the Company to provide a security deposit. Certain leases provide the right for the Company to renew the lease upon the expiration of the initial lease term, and various leases have scheduled rent increases on an annual basis. The exercise

of lease renewal options for the Company's existing leases is at the Company's sole discretion, and not included in the measurement of right-of-use asset or lease liability as they are not reasonably certain to be exercised.

The Company's lease costs consisted of the following (in thousands):

	Year Ended December 31,	
	2025	2024
Operating lease cost	$ 1,555	$ 1,315
Variable lease cost	704	801
Total lease cost	$ 2,259	$ 2,116

The following table summarizes cash flow information related to the Company's lease obligations (in thousands):

	Year Ended December 31,	
	2025	2024
Cash paid for operating lease liabilities	$ 1,545	$ 2,279

The following table summarizes the Company's lease assets and liabilities (in thousands):

	December 31,	
	2025	2024
Operating lease right-of-use assets	$ 238	$ 934
Current operating lease liabilities	$ 372	$ 1,682
Non-current operating lease liabilities	$ —	$ 1,017

The following table summarizes other supplemental information related to the Company's lease obligations:

	December 31,	
	2025	2024
Weighted-average remaining lease term (in years)	0.70	1.70
Weighted-average discount rate	6.75 %	6.75 %

Future minimum lease payments under operating lease liabilities were $0.4 million as of December 31, 2025 which are recorded in the line item "accrued expenses and other current liabilities" in the consolidated balance sheet.

During the years ended December 31, 2025 and 2024, the Company evaluated its remaining right-of-use assets for impairment, as the Plan (as defined below in Note 13) has resulted in a cessation of use for the United Kingdom locations. The Company determined these assets were impaired and recognized an impairment loss of nil and $0.8 million for the years ended December 31, 2025 and 2024, respectively, which are recorded in the line item "restructuring and impairment charges" in the consolidated statements of operations and comprehensive loss.

Company's Subsidiary as a Lessor: Tarzana Facility Lease with AstraZeneca

On July 10, 2024, Complex Therapeutics LLC, a wholly owned subsidiary of the Company, entered into a lease with AstraZeneca Pharmaceuticals LP ("Tenant") pursuant to which Tenant is leasing the facility located in Tarzana, California (the "Lease"). The Lease has an initial term of approximately 15 years, beginning on July 10, 2024 and ending on July 31, 2039, with Tenant having two consecutive options to extend the term for a five-year period each and a one-time option to terminate the Lease on the tenth anniversary of the commencement of the Lease, which, if exercised, obligates Tenant to pay Complex Therapeutics LLC a termination fee. The initial base rent was approximately $0.6 million per month (approximately $7.5 million annually) and the base rent escalates by 3% per annum. Tenant is also required to pay certain operating expenses and tax expenses as additional rent. There was rent abatement during the first year of the Lease such that Tenant paid no rent or reduced rent during this period. Tenant also has a right of first offer to purchase the premises that are subject to the Lease.

The Lease is classified as an operating lease and revenue is recognized on a straight-line basis and is recorded within the consolidated statements of operations and comprehensive loss in the line item “Other rental income” as this is not a part of the Company’s core operations. Rental income related to the Lease was as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Rental income related to fixed lease income	$ 8,968	$ 4,267

Approximate future straight-lined contractual lease income to be recognized under the lease in effect as of December 31, 2025 is as follows (in thousands):

	December 31, 2025
2026	$ 8,968
2027	8,968
2028	8,968
2029	8,968
2030	8,968
Thereafter	76,974
Total	$ 121,814

Differences between rental income earned and amounts due per the Lease is capitalized or charged, as applicable, to accrued rent receivable. As of December 31, 2025 and December 31, 2024, the Company had accrued rent receivable of $7.7 million and $4.3 million, respectively.

Legal Proceedings

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of its business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and that such expenditures can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount. The Company does not expect that the resolution of these matters will have a material adverse effect on its financial position, results of operations or cash flows.

Debt

In June 2022, the Company’s wholly owned subsidiaries, Complex Therapeutics Mezzanine LLC and Complex Therapeutics LLC entered into a mortgage construction loan and mezzanine construction loan (together, the “Construction Loans”) secured by Complex Therapeutic LLC's Tarzana, California land and building. The initial principal amount of the Construction Loans was $52.1 million, with additional future principal of up to $32.9 million to fund ongoing construction costs. The Construction Loans were guaranteed by the Company and bore interest at the one-month Secured Overnight Financing Rate, plus 5.25% per annum. On July 10, 2024, Complex Therapeutics LLC entered into the Lease. On December 20, 2024, Complex Therapeutics LLC refinanced the outstanding principal amount under the Construction Loans and the Company treated it as a loan extinguishment for accounting purposes and recorded the $0.4 million of unamortized debt issuance costs associated with the Construction Loans as a loss on debt extinguishment recognized in other expense, net in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2024.

On December 20, 2024, Complex Therapeutics LLC entered into a Term Loan Agreement (the “2024 Loan”) and related loan documents with Midland National Life Insurance Company (“Midland”), pursuant to which Midland loaned Complex Therapeutics LLC a term loan in the principal amount of $85.6 million to refinance the Construction Loans. Substantially all of the 2024 Loan proceeds were used to repay in full the Construction Loans. As of December 31, 2025, the outstanding principal amount under the 2024 Loan was $85.6 million and unamortized debt issuance costs were $0.8 million.

The 2024 Loan has a term of two years with a one-year extension option. The extension option is subject to certain conditions being met, including: (a) no potential default or event of default, (b) payment of a 0.35% extension fee and the costs and expenses of Midland incurred in connection with the extension, (c) replenishing of all reserve funds as reasonably determined by Midland, and (d) compliance with minimum debt yield and debt service coverage ratio requirements. The 2024 Loan bears interest at a fixed rate of 6.35% per annum, with interest-only payments during the term of the 2024 Loan and the principal balance due in full at maturity. The Company expects Complex Therapeutics LLC to meet all requirements necessary to exercise the extension.

The 2024 Loan may be prepaid in whole but not in part. If the 2024 Loan is prepaid on or prior to the 12-month anniversary of the Closing Date, a prepayment fee is required (other than in connection with a casualty or condemnation event) to make Midland whole for the interest it would have otherwise earned on the 2024 Loan during the first 12 months. There is no prepayment fee due if the 2024 Loan is prepaid after the 12-month anniversary of the Closing Date.

The net carrying amount of the liability component of the 2024 Loan was as follows (in thousands):

	December 31,	
	2025	2024
Principal amount	$ 85,600	$ 85,600
Unamortized debt issuance cost	(794)	(1,413)
Net carrying amount	$ 84,806	$ 84,187

The following table sets forth the interest expense recognized related to the 2024 Loan and Construction Loans (in thousands):

	Year Ended December 31,	
	2025	2024
Contractual interest expense	$ 5,038	$ 7,997
Amortization of debt issuance cost	791	995
Total interest expense related to the loans	$ 5,829	$ 8,992

Indemnifications

The Company has entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Delaware corporate law. The Company currently has directors' and officers' insurance coverage that reduces its exposure and enables the Company to recover a portion of any future amounts paid. No liability associated with such indemnifications was recorded as of December 31, 2025 and 2024.

Other Commitments

In the normal course of business, the Company enters into contracts and various purchase agreements and commitments with third-party vendors for clinical research services, products and other services for operating purposes. These agreements generally provide for termination or cancellation at the Company's option, other than for costs already incurred.

As of December 31, 2025 and 2024, the Company had nil and $0.1 million outstanding liabilities, respectively, in commitments for employee benefits as part of the Plan (see Note 13). As of December 31, 2025 and 2024, the Company had $0.2 million and $1.9 million, respectively, in commitments for contract terminations as part of the Plan. (see Note 13).

The Company entered into an agreement in 2023 with a third-party collaborator in China related to the development of the Company's CoStAR-TIL technology; this agreement was subsequently terminated in 2025. Milestone payments of nil and $2.6 million were made during the year ended December 31, 2025 and 2024,

respectively, and were recorded within research and development expense in the consolidated statements of operations and comprehensive loss.

9. Equity

Common Stock

Each share of common stock has the right to one vote. The holders of common stock are also entitled to receive dividends out of legally available funds when and if declared by the Company's Board of Directors, subject to the rights of holders of any classes of stock outstanding having priority rights as to dividends. No cash dividends have been declared by the Board of Directors from inception.

As of December 31, 2025 and 2024, the Company had 6,781,976 and 6,525,887 shares of common stock outstanding, respectively.

At-the-Market Offering (ATM Program)

In March 2025, the Company entered into an Open Market Sale Agreement℠ with Jefferies LLC ("Jefferies") pursuant to which the Company may, subject to the terms and conditions set forth in the agreement, offer and sell, from time to time, through or to Jefferies, acting as agent or principal, shares of common stock having an aggregate offering price of up to $100.0 million in one or more "at the market offerings" (the "ATM Program").

During the year ended December 31, 2025, the Company sold 185,837 shares of common stock under the ATM Program at a weighted-average price of $37.13 per share, for net proceeds of $6.6 million, after deducting commissions and expenses of approximately $0.3 million. The remaining availability under the ATM Program as of December 31, 2025 is approximately $93.1 million.

Preferred Stock

The Company's current amended and restated certificate of incorporation authorizes the Company to issue up to 10,000,000 shares of preferred stock at $0.000001 par value per share. The Board of Directors is authorized to provide for the issuance of the preferred stock in one or more series, and to fix the number of shares and to determine or alter for each such series, such voting powers, full or limited, or no voting powers, and such designation, preferences, and relative, participating, optional, or other rights and such qualifications, limitations, or restrictions thereof, as shall be stated and expressed in subsequent resolution or resolutions adopted by the board providing for the issuance of such shares. As of December 31, 2025 and 2024 there were no shares of preferred stock issued or outstanding.

10. Stock-Based Compensation

2021 Equity Incentive Plan

In March 2021, the Company adopted the 2021 Equity Incentive Plan (the "2021 Plan"), which became effective in connection with the Company's initial public offering ("IPO"). The 2021 Plan was approved by the Board of Directors and stockholders in March 2021. The 2021 Plan is an equity incentive plan pursuant to which the Company may grant the following awards: (i) incentive stock options; (ii) nonstatutory stock options; (iii) stock appreciation rights; (iv) restricted stock awards; (v) restricted stock unit awards; (vi) performance awards; and (vii) other forms of stock awards to employees, directors, and consultants, including employees and consultants of the Company's affiliates. The 2021 Plan is a successor to the Company's 2018 Stock Incentive Plan (the "2018 Plan"). Following the effectiveness of the 2021 Plan, no further grants may be made under the 2018 Plan; however, any outstanding equity awards granted under the 2018 Plan will continue to be governed by the terms of the 2018 Plan.

The number of shares available for future issuance under the 2021 Plan is the sum of (1) 433,000 new shares of common stock, (2) 209,722 remaining shares of common stock reserved under the 2018 Plan that became available for issuance upon the effectiveness of the 2021 Plan and (3) the number of shares of common stock subject to

outstanding awards under the 2018 Plan when the 2021 Plan became effective that thereafter expire or are forfeited, canceled, withheld to satisfy tax withholding or to purchase or exercise an award, repurchased by the Company or are otherwise terminated. The number of shares of common stock reserved for issuance under the 2021 Plan will automatically increase on January 1 of each year, for a period of ten years, from January 1, 2022 continuing through January 1, 2031, by 5% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares as may be determined by the Company's Board of Directors. Stock options granted by the Company to employees generally vest over four years with a one-year cliff.

As of December 31, 2025, 481,355 shares of common stock remained available for issuance under the 2021 Plan.

The following table sets forth stock-based compensation included in the Company's consolidated statements of operations and comprehensive loss (in thousands):

	Shares Available for Grant	Shares Issuable Under Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contract Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance, December 31, 2023	659,608	799,622	$ 87.90	7.18	$ 101
Additional shares authorized	325,196				
Options granted	(546,800)	546,800	$ 29.19		
Options forfeited	74,989	(74,989)	$ 132.63		
Options exercised	—	(21,974)	$ 16.64		
Balance, December 31, 2024	512,993	1,249,459	$ 60.78	7.31	$ 4,827
Additional shares authorized	325,012	1,250			
Options granted	(562,010)	562,010	$ 17.58		
Options forfeited	205,360	(205,360)	$ 63.25		
Options exercised	—	(70,252)	$ 12.13		
Balance, December 31, 2025	481,355	1,537,107	$ 46.84	7.26	$ 515
Exercisable, December 31, 2025		820,027	$ 66.48	5.83	$ 515
Vested and expected to vest, December 31, 2025		820,027	$ 66.48	5.83	$ 515

The aggregate intrinsic value disclosed in the above table is based on the difference between the exercise price of the stock option and the estimated fair value of the Company's common stock as of the respective period-end dates. There were 70,252 and 21,974 stock options exercised during the years ended December 31, 2025 and 2024, respectively. The aggregate intrinsic value of stock options exercised was zero and $0.1 million during the years ended December 31, 2025 and 2024, respectively. The weighted-average grant date fair value of stock options granted during the years ended December 31, 2025 and 2024, was $14.13 and $22.85 per share, respectively.

The following table sets forth stock-based compensation included in the Company's consolidated statements of operations and comprehensive loss (in thousands):

	Year Ended December 31,	
	2025	2024
Research and development expense	$ 779	$ 2,066
General and administrative expense	7,914	15,191
Total stock-based compensation expense	$ 8,693	$ 17,257

As of December 31, 2025 and 2024, there was $12.6 million and $16.6 million, respectively, of total unrecognized compensation cost related to unvested stock options granted under the 2018 Plan and 2021 Plan, which is expected to be recognized over a weighted average period of 2.35 years and 2.25 years, respectively.

The fair value of the Company's stock option awards was estimated at the date of grant using a Black-Scholes option pricing model with the following assumptions:

	Year Ended December 31,	
	2025	2024
Expected term (in years)	5.28 — 6.08	5.27 — 6.08
Expected volatility	98.18 % — 102.67%	86.92 % — 100.06%
Risk-free interest rate	3.87 % — 4.19%	3.53 % — 4.57%
Fair value of common stock	$12.78 — $30.33	$10.50 — $66.10
Expected dividend yield	—%	—%

The Black-Scholes option pricing model requires the use of highly subjective assumptions which determine the fair value of stock-based awards. These assumptions include:

Expected term—The expected term represents the period that stock-based awards are expected to be outstanding and is determined as the average of the time-to-vesting and the contractual life of the awards.

Expected volatility—Since the Company is privately held and does not have any trading history for its common stock, the expected volatility was estimated based on the average volatility for comparable publicly traded biotechnology companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty.

Risk-free interest rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of awards.

Expected dividend yield—The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

Employee Stock Purchase Plan

In March 2021, the Company adopted the Employee Stock Purchase Plan (the "ESPP"), which became effective in connection with the IPO. The ESPP was adopted by the Board of Directors and stockholders in March 2021, but the Company has not yet commenced offerings to employees under the ESPP. The ESPP initially provides participating employees with the opportunity to purchase up to an aggregate of 61,850 shares of common stock. The number of shares reserved under the ESPP automatically increases on January 1 of each year through and until January 1, 2031, in an amount equal to the lesser of (i) 1% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, and (ii) 123,700 shares; provided, however, that before the date of any such increase, the Board of Directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii).

11. Net Loss Per Share

The following outstanding potentially dilutive shares have been excluded from the calculation of diluted net loss per share for the periods presented due to their anti-dilutive effect:

	December 31,	
	2025	2024
Stock options to purchase common stock	1,537,107	1,249,459

12. Income Taxes

The geographical breakdown of loss before provision for income taxes is as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Domestic	$ (69,021)	$ (60,382)
Foreign	(2,351)	(13,753)
Loss before income taxes	$ (71,372)	$ (74,135)

The Company had no income tax expense for both domestic and foreign jurisdictions for the years ended December 31, 2025 and 2024.

A reconciliation of the provision for income taxes to the amount computed by applying the 21% statutory U.S. federal income tax rate to income before income taxes after the adoption of ASU 2023-09 is as follows (in thousands, except percentages):

	Year Ended December 31, 2025	
	$ Amount	%
U.S. federal taxes at statutory rate	(14,980)	21.0 %
Foreign tax effects:		
United Kingdom:		
Stock-based compensation	1,032	(1.5)%
Other	(538)	0.8 %
State and local income taxes	—	— %
Nontaxable or non-deductible items:		
Stock-based compensation	2,879	(4.0)%
Other	(174)	0.2 %
Changes in valuation allowance	11,777	(16.5)%
Other	4	— %
Total income tax expense and effective tax rate	$ —	— %

A reconciliation of the provision for income taxes to the amount computed by applying the 21% statutory U.S. federal income tax rate to income before income taxes for the year prior to the adoption of ASU 2023-09 is as follows:

	Year Ended December 31,
	2024
U.S. federal taxes at statutory rate	21.0 %
Stock-based compensation	(6.7)%
Permanent differences and other	0.3 %
Statutory tax rate differences	4.4 %
Change in valuation allowance	(19.0)%
Total	— %

The components of deferred tax liabilities consist of the following (in thousands):

	Year Ended December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 109,397	$ 95,773
Research and development credits	4,915	4,915
Accrued compensation and benefits	681	646
Stock-based compensation	520	2,008
Capitalized research and development	18,277	20,920
Other temporary differences	9,270	10,201
Intangible assets	5,347	2,841
Fixed assets	6,883	4,827
Other	753	426
Total gross deferred tax assets	156,043	142,557
Less: valuation allowance	(153,905)	(141,367)
Total deferred tax assets, net	2,138	1,190
Deferred tax liabilities:		
Rent receivable	(2,138)	(1,190)
Total gross deferred tax liabilities	(2,138)	(1,190)
Net deferred tax assets (liabilities)	$ —	$ —

The components of unrecognized tax benefits consist of the following (in thousands):

Balance at December 31, 2024	$ 2,339
Additions in 2025	—
Balance at December 31, 2025	$ 2,339

In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Due to the uncertainty of the business in which the Company operates, projections of future profitability are difficult and past profitability is not necessarily indicative of future profitability. The Company does not believe it is more likely than not that the deferred tax assets will be realized, and accordingly, the valuation allowance increased $12.5 million for the year ended December 31, 2025. As of December 31, 2025, the Company had net operating loss carryforwards for federal income tax purposes of $405.4 million, which will carryforward indefinitely, but may only offset 80% of the Company's taxable income. This limitation on the net operating loss may require the Company to pay federal income taxes in future years despite generating a loss for federal income tax purposes in prior years. In addition, the Company has $136.1 million of California net operating loss carryforwards available to reduce future state taxable income as of the year ended December 31, 2025. The state net operating loss carryforwards will begin to expire, if not utilized, in 2044.

The Company has R&D credits of $4.1 million, and $3.7 million for federal and California, respectively, as of December 31, 2025. The federal R&D credits expire in 2043 and the California R&D credits carryforward indefinitely.

Upon the prospective adoption of ASU 2023-09 the Company is required to disclose income taxes paid, net of refunds for 2025. All amounts for federal, state and foreign are zero for the year ended December 31, 2025.

The Company files income tax returns in the U.S. federal jurisdiction, various states where the Company has employees and/or significant business activities, and the United Kingdom. As of December 31, 2025, the Company's federal and state returns through 2022 are still open to examination. The UK returns starting from 2024

are open to examination. The Company had uncertain tax positions as of December 31, 2024 of $2.3 million and this balance remained unchanged during December 31, 2025. The Company does not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease during the next 12 months. The Company had no accrued interest or penalties related to uncertain tax positions as of December 31, 2025.

The Company has not completed a Section 382 study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since the Company's formation. Pursuant to Internal Revenue Code Sections 382 and 383, annual use of the Company's net operating loss and research and development tax credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. Due to the existence of the valuation allowance, limitations created by future ownership changes, if any, are not anticipated to impact the Company's effective tax rate.

13. Corporate Restructuring Plan

In January 2023, the Board of Directors approved a restructuring plan (referred to as the "2023 Plan") and the Company announced the consolidation of the ITIL-306 Phase 1 clinical trial and related manufacturing of CoStAR-TIL to its operations in Manchester, UK and stopped recruiting for the ITIL-306 clinical trial.

In January 2024, the Board of Directors approved a comprehensive restructuring plan, which included the closure of the Company's UK manufacturing facility and clinical trial operations. In September 2024, the Board of Directors approved additional UK restructuring actions, which resulted in the elimination of the majority of the remaining UK workforce in the fall of 2024, with the remaining reduction and restructuring activities substantially completed by the end of 2024. Collectively, these actions are referred to as the "2024 Plan."

The 2023 Plan and 2024 Plan are collectively referred to as the "Plan".

Restructuring and Impairment Charges

As a result of the Plan and listing the Tarzana facility for sale, the Company recorded charges of $16.6 million and $7.5 million within the consolidated statements of operations and comprehensive loss in the line item "restructuring and impairment charges" for the years ended December 31, 2025 and 2024, respectively.

These charges relate to asset impairments, contract terminations, severance payments, employee-related costs and other gains incurred. The following table summarizes the restructuring and impairment (gain) loss by category (in thousands):

	Year Ended December 31,	
	2025	2024
Asset impairment for leasehold improvements	$ —	$ 343
One-time employee termination benefits	—	2,721
Contract terminations	53	(723)
Right-of-use asset impairment	—	827
Impairment of long-lived assets held for sale	16,569	4,325
Total restructuring and impairment charges	$ 16,622	$ 7,493

Restructuring Liability

As a result of the Plan, the restructuring liability was recorded in the consolidated balance sheets under "Accrued expenses and other current liabilities" and was measured at the amount expected to be paid, or that was paid. During the year ended December 31, 2025, the Company paid $1.4 million of restructuring costs, and expects to pay the remainder of the restructuring costs by December 31, 2026.

The following table shows the liability related to the Plan (in thousands):

	Employee Benefits	Contract Terminations	Total
Restructuring liability as of December 31, 2023	$ —	$ 3,136	$ 3,136
Additions, net	2,420	733	3,153
Payments	(2,289)	(578)	(2,867)
Adjustments	—	(1,349)	(1,349)
Restructuring liability as of December 31, 2024	$ 131	$ 1,942	$ 2,073
Payments	(131)	(1,300)	(1,431)
Adjustments	—	(487)	(487)
Total restructuring liability as of December 31, 2025	$ —	$ 155	$ 155

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, with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2025, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's Board of Directors, management and other personnel, 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 and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;
- 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
- 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.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2025 based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in its 2013 Internal Control - Integrated Framework. Based on its assessment, our management has concluded that our internal over financial reporting was effective as of December 31, 2025.

This Annual Report on Form 10-K does not include an attestation report of our independent public accounting firm as allowed by Section 404(b) of the Sarbanes-Oxley Act, as amended by Section 103 of the JOBS Act.

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 quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, do not expect that our disclosure controls or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a 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 management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Item 9B. Other Information.

During the quarter ended December 31, 2025, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted, modified or terminated a “Rule 10b5-1 trading arrangement” or a “non-Rule 10b5-1 trading arrangement” (as each term is defined in Item 408 of Regulation S-K).

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

Part III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item and not set forth below will be set forth in the sections captioned "Election of Directors," "Information Regarding the Board of Directors and Corporate Governance," "Executive Officers" and "Delinquent Section 16(a) Reports", if applicable, in our definitive Proxy Statement for our 2026 Annual Meeting of Stockholders to be filed with the SEC on or before April 30, 2026, or the 2026 Proxy Statement, and is incorporated in this report by reference.

We have adopted a code of ethics for directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, known as the Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics is available on our website at http://www.instilbio.com under the Corporate Governance section of our Investors page. We will promptly disclose on our website (i) the nature of any amendment to the policy that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals, the name of such person who is granted the waiver and the date of the waiver.

We have adopted an Insider Trading Policy governing the purchase, sale and/or other dispositions of our securities by our directors, officers and employees. A copy of the Insider Trading Policy is filed as an exhibit to this Annual Report on Form 10-K. In addition, it is the Company's practice to comply with the applicable laws and regulations relating to insider trading.

Item 11. Executive Compensation.

The information required by this Item will be set forth under the sections captioned "Executive Compensation" and "Director Compensation" in the 2026 Proxy Statement and is incorporated in this report by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item will be set forth under the sections captioned "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance under Equity Compensation Plans" in the 2026 Proxy Statement and is incorporated in this report by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item will be set forth under the sections captioned "Transactions with Related Persons and Indemnification" and "Information Regarding the Board of Directors and Corporate Governance—Independence of the Board of Directors" in the 2026 Proxy Statement and is incorporated in this report by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this Item will be set forth under the section captioned "Ratification of Selection of Independent Registered Public Accounting Firm" in the 2026 Proxy Statement and is incorporated in this report by reference.

Part IV

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, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

INSTIL BIO, INC.

March 27, 2026

By: /s/ Bronson Crouch
Bronson Crouch
Chief Executive Officer

Signatures And Power of Attorney

Know all persons by these presents, that each person whose signature appears below constitutes and appoints Bronson Crouch and Sandeep Laumas, M.D., jointly and each one of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place, and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Bronson Crouch Bronson Crouch	Chief Executive Officer and Chairman (Principal Executive Officer)	March 27, 2026
/s/ Sandeep Laumas, M.D. Sandeep Laumas, M.D.	Chief Financial Officer and Chief Business Officer (Principal Financial and Accounting Officer)	March 27, 2026
/s/ Gwendolyn Binder, Ph.D. Gwendolyn Binder, Ph.D.	Director	March 27, 2026
/s/ Neil Gibson, Ph.D. Neil Gibson, Ph.D.	Director	March 27, 2026
/s/ George Matcham, Ph.D. George Matcham, Ph.D.	Director	March 27, 2026
/s/ R. Kent McGaughy, Jr. R. Kent McGaughy, Jr.	Director	March 27, 2026