2025 ANNUAL REPORT

Included in the 2025 Annual Report:
Form 10-K (without exhibits) filed with the U.S. Securities and Exchange Commission on March 23, 2026

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

OR

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

For the transition period from _____to_____

Commission File No. 001-37590

AVALO THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	45-0705648
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1500 Liberty Ridge Drive, Suite 321
Wayne, Pennsylvania 19087
(Address of principal executive offices)
Telephone: (410) 522-8707
(Registrant's telephone number, including area code)
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, $0.001 Par Value	AVTX	Nasdaq Capital Market

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule12b-2 of the Exchange Act.

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

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

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the registrant’s shares of common stock held by non-affiliates of the registrant as of June 30, 2025 (which is the last business day of the registrant's most recently completed second fiscal quarter) based upon the closing market price of such stock on the Nasdaq Capital Market on that date was approximately $53.7 million. Shares of common stock held by each officer and directors and by each person known to be the registrant who owned 10% or more of the outstanding common stock have been excluded in that such person may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 18, 2026, there were 22,788,452 outstanding shares of the registrant’s common stock, par value $0.001 per share.

TABLE OF CONTENTS

PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report and the information incorporated herein by reference contain forward-looking statements that involve a number of risks and uncertainties, as well as assumptions that, if they never materialize or if they prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements.

Forward-looking statements can be identified by the use of forward-looking words such as "projects," "may," "might," "will," "could," "would," "should," "continue," "seeks," "aims," "predicts," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential," "pro forma" or other similar words (including their use in the negative), or by discussions of future matters such as: the future financial and operational outlook; the development of product candidates; and other statements that are not historical. These statements include but are not limited to statements under the captions "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" as well as other sections in this report. You should be aware that the occurrence of any of the events discussed under the caption "Risk Factors" and elsewhere in this report could substantially harm our business, results of operations and financial condition and cause our results to differ materially from those expressed or implied by our forward-looking statements. If any of these events occurs, the trading price of our common stock and the price or value of our other securities could decline and you could lose all or a part of the value of your investment in our Company.

The cautionary statements made in this report are intended to be applicable to all related forward-looking statements wherever they may appear in this report. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

As used in this report, the terms "Avalo," "Company," "we," "us," and "our" mean Avalo Therapeutics, Inc. and its subsidiaries unless the context indicates otherwise.

SUMMARY OF PRINCIPAL RISK FACTORS

This summary briefly states the principal risks and uncertainties facing our business that could affect our securities, which are only a select portion of those risks. A more complete statement of those risks and uncertainties is set forth under Part I, Item 1A "Risk Factors" of this Annual Report on Form 10-K. This summary is qualified in its entirety by that more complete statement. You should carefully read the entire "Risk Factors" section when considering the risks and uncertainties as part of your evaluation of our business and your investment in our company.

- If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

- If we experience delays in clinical testing, we will be delayed in obtaining regulatory approvals and commercializing our product candidates, our costs may increase and our business may be harmed.

- Even if we complete the necessary clinical trials, we cannot predict when or if we will obtain marketing approval to commercialize a product candidate or the approval may be for a narrower indication than we expect or may be conditioned on costly post-approval obligations.

- We rely on third parties to conduct and monitor our clinical trials. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could hinder our ability to commercialize or obtain marketing approval for our product candidates in a timely manner, or at all.

- Our product candidates that we intend to commercialize are in early to mid-stages of development. If we do not successfully complete nonclinical testing and clinical development of our product candidates or experience significant delays in doing so, our business may be materially harmed. Our focus and reliance on abdakibart (AVTX-009) increases the risk of such exposure.

- We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Our focus and reliance on abdakibart (AVTX-009) increases the risk of such exposure.

- The marketing approval processes of the United States Food and Drug Administration (the "FDA") and other regulatory authorities are lengthy, time-consuming, costly and inherently unpredictable. Our inability to obtain regulatory approval for our product candidates would substantially harm our business and prospects.

- We use third parties to manufacture all of our product candidates. This may increase the risk that we will not have sufficient clinical or commercial quantities of our product candidates, or such quantities at an acceptable cost, which could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates and could harm our business, financial condition and results of operations.

- We expect to require additional capital in the future to continue to fund our operations and to finance the further advancement of our product candidates, which might not be available to us on acceptable terms, or at all. Failure to obtain any necessary capital could force us to delay, limit or terminate our product development efforts or significantly curtail or cease our operations altogether.

- Even if we receive marketing approval for abdakibart (AVTX-009) or future product candidates, our current or future product candidates may not achieve broad market acceptance, which would limit the revenue that we generate from their sales and could prevent us from achieving or sustaining profitability.

- If we are unable to obtain or maintain intellectual property rights, or if the scope of patent protection is not sufficiently broad, competitors could develop and commercialize products similar or identical to ours, and we might not be able to compete effectively in that market. Furthermore, our US composition-of-matter patent for abdakibart (AVTX-009) expired in February 2026.

- If we breach the license and development agreements related to our product candidates, we could lose the ability to develop and commercialize our product candidates.

- If we fail to attract and keep management and other key personnel, as well as members of our board of directors, we may be unable to develop our product candidates or otherwise implement our business plan.

- The price of our common stock could be subject to rapid and substantial volatility. Such volatility, including any stock run-ups, may be unrelated to our actual or expected operating performance and financial condition or prospects, making it difficult for prospective investors to assess the rapidly changing value of our common stock. Volatility in our common stock price may subject us to securities litigation or regulatory scrutiny.

- We have incurred significant net losses in most periods since our inception and we expect to continue to incur net losses in the future.

- We or the third parties upon whom we depend may be adversely affected by unforeseen global events, natural disasters, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

PART I

Item 1. Business.

Overview

We are a clinical stage biotechnology company fully dedicated to developing IL-1β-based treatments for immune-mediated inflammatory diseases. Our lead product candidate, abdakibart (AVTX-009), an anti-IL-1β monoclonal antibody ("mAb") is in a Phase 2 clinical trial for hidradenitis suppurativa ("HS"). We are also exploring additional opportunities to make an impact in prevalent indications that have significant remaining unmet needs.

Our current focus is on completing the Phase 2 ("LOTUS") trial evaluating abdakibart (AVTX-009) in HS, preparing for the anticipated topline data readout in the second quarter of 2026, and planning for our Phase 3 trial(s).

Our Strategy

Our strategy for increasing stockholder value includes:

- Advancing our pipeline through development to regulatory approval—notably and in the near term, by completing our Phase 2 LOTUS trial in HS, preparing to initiate our pivotal trial(s) pending the readout of the Phase 2 LOTUS trial results and considering further indication expansion for abdakibart (AVTX-009);
- Acquiring or in-licensing rights to and/or developing targeted, complementary differentiated preclinical and clinical stage compounds that treat immune-mediated inflammatory disease; and
- Opportunistically out-licensing rights to compounds, indications or geographies.

Pipeline - Overview, Competition, and Intellectual Property

We are advancing a pipeline that emphasizes a high-value and potentially best-in-class and best-in-disease biologics for immune mediated inflammatory diseases.

The following table summarizes certain key information about our lead product candidate:

Abdakibart (AVTX-009): *Anti-IL-1β mAb targeting inflammatory diseases.*

Our lead product candidate, abdakibart (AVTX-009), is a high affinity, highly potent humanized IgG mAb designed to specifically inhibit IL-1β and block downstream inflammatory pathways. Abdakibart (AVTX-009) is a humanized monoclonal antibody (IgG4) that binds to interleukin-1β ("IL-1β") with high affinity and neutralizes its activity. IL-1β is a pro-inflammatory cytokine that plays a central role in the pathogenesis of a wide range of human diseases. It activates immune cells that generate proinflammatory cytokines, including IL-6, TNF-α, and IL-17. Dysregulated IL-1β signaling is a major driver of inflammation, contributing to the progression of autoimmune disorders. IL-1β inhibition has proven effective in multiple immune-mediated inflammatory diseases. Abdakibart (AVTX-009) has previously been referred to as FL-101 and LY2189102, when rights in it were held by Leap Therapeutics (previously Flame Biosciences) and Eli Lilly and Company, respectively. Abdakibart (AVTX-009) is currently being studied in the LOTUS Phase 2 trial in participants with HS. In October 2025, we announced that we completed enrollment in the Phase 2 LOTUS trial and expect to report topline data in the second quarter of 2026.

Phase 2 LOTUS Trial

The LOTUS trial (NCT06603077) is a randomized, double-blind, placebo-controlled, parallel-group Phase 2 trial with two abdakibart (AVTX-009) dosing regimens to evaluate the efficacy, safety and tolerability of abdakibart (AVTX-009) in approximately 250 adults with moderate to severe hidradenitis suppurativa. Subjects were randomized (1:1:1) to receive either one of two dosing regimens of abdakibart (AVTX-009) or placebo during a 16-week treatment phase. The primary efficacy endpoint is the proportion of subjects achieving Hidradenitis Suppurativa Clinical Response 75 (HiSCR75) at Week 16.

Secondary objectives include but are not limited to: the proportion of patients achieving HiSCR50 and HiSCR90 as well as change from baseline in: International HS Severity Score System (IHS4), draining fistula count, abscess and inflammatory nodule (AN) count, and patients achieving at least a 30% reduction on a numerical rating scale in Patient's Global Assessment of Skin Pain (PGA Skin Pain). We are the study sponsor and current trial site locations include the United States, Canada, France, Germany, Italy, Spain, Bulgaria, Czech Republic, Greece, Poland, Australia, Turkey, and Slovakia.

Development Opportunity in HS

IL-1β is a pro-inflammatory cytokine that plays a central role in the pathogenesis of a wide range of human diseases. IL-1β activates immune cells that generate proinflammatory cytokines, including IL-6, TNF-α, and IL-17. Dysregulated IL-1β signaling is a major driver of inflammation, contributing to the progression of autoimmune disorders.

IL-1β inhibition has proven effective in multiple immune-mediated inflammatory diseases. IL-1β also has a well-established class safety and tolerability profile supported by ILARIS® (canakinumab), an IL-1β blocker approved for use in multiple indications.

HS is a chronic, progressive, often debilitating inflammatory skin disease that causes painful nodules, abscesses, and tunnels to form under the skin. Areas commonly affected by HS include the nape of the neck, breasts, chest, armpits, abdomen, buttocks and anus, groin and genitals, and inner thighs. If not adequately or promptly treated, the chronic inflammation characteristic of HS may progress to tissue destruction and permanent scarring. HS typically first presents in late adolescence or early adulthood and is estimated to affect 0.7–1.2% of the U.S. population, though some sources suggest the prevalence may be as high as 2–4%.

There is a substantial unmet need for more effective and durable treatment options in HS. Currently approved biologics for HS (adalimumab (anti-TNF-α), secukinumab (anti-IL-17A), and bimekizumab (dual anti-IL-17A/F)) achieve HiSCR50 (an efficacy measure) only ~50% of the time, with more stringent thresholds (HiSCR75/90) achieved in even fewer individuals. Long-term disease control remains a challenge with established biologics and an area of uncertainty with newer agents (secukinumab and bimekizumab), as data on sustained efficacy are still emerging. In addition, people with HS often have comorbidities that can limit access to current treatment options.

There were an estimated 3.4 million people in the United States with HS in 2024 with such number expected to rise to 3.5 million by 2035. Additionally, it is estimated that HS affects approximately 1-4% of the population worldwide. Of the 3.4 million people who were estimated to have HS in the United States in 2024, only approximately 1.0 million were diagnosed and treated, with this number projected to rise to 1.6 million by 2035. The global HS market is expected to grow to >$10 billion by 2035.

Legacy Programs

We are not currently pursuing the clinical development of the following legacy programs and are exploring strategic alternatives for them.

Quisovalimab (AVTX-002): Quisovalimab is fully human mAb, directed against human LIGHT (Lymphotoxin-like, exhibits Inducible expression, and competes with HSV Glycoprotein D for Herpesvirus Entry Mediator, a receptor expressed by T lymphocytes; also referred to as TNFSF14).

- **AVTX-006**: AVTX-006 is a dual mTORc1/c2 small molecule inhibitor.
- **AVTX-008**: AVTX-008 is a fully human B and T Lymphocyte Attenuator agonist fusion protein.
- **AVTX-913**: AVTX-913 is a nucleotide prodrug for the treatment of a mitochondrial disorder and is a preclinical asset.

Licensing and Partnerships

Eli Lilly License Agreement

Abdakibart (AVTX-009) is subject to a world-wide exclusive license from Eli Lilly and Company ("Lilly") (the "Lilly License Agreement"), as well as an agreement under which AlmataBio, Inc. ("AlmataBio") purchased rights to the compound from Leap Therapeutics, Inc. ("Leap" and the "Leap Agreement"). We obtained the rights to abdakibart (AVTX-009), including the Lilly License Agreement and Leap Agreement, pursuant to our acquisition of AlmataBio in the first quarter of 2024 (the "AlmataBio Transaction"). We are responsible for the development and commercialization of the program.

We are required to pay Lilly up to $70 million based on the achievement of specified development and regulatory milestones. Upon commercialization, we are required to pay sales-based milestones aggregating up to $650 million payable to Lilly and up to $70 million to Leap.

Additionally, we are required to pay royalties to Lilly of between 5% and 15% of Avalo or its sublicensees' annual net sales, beginning on first commercial sale of a licensed product in a given territory and expiring on a country-by-country basis, on the latest of (a) the tenth (10th) anniversary of the date of the first commercial sale, (b) the expiration of the last-to-expire licensed patent in the given country, or (c) the expiration of any data exclusivity period for the licensed product in the given territory.

We have not paid any milestones, royalties or any other amounts under the Lilly License Agreement or the Leap Agreement as of the date of this report. Additionally, there are no annual or maintenance fees payable under the Lilly License Agreement or the Leap Agreement.

The Lilly License Agreement remains in effect until the expiration of the last-to-expire royalty term of any licensed products. Each party may terminate for cause, and though we may terminate at our sole discretion by giving one-hundred twenty (120) days' prior written notice to Lilly, all licenses and rights granted pursuant to the agreement shall automatically terminate and revert to Lilly. There are no termination or expiration provisions under the Leap Agreement.

AlmataBio Transaction

Pursuant to the AlmataBio Transaction, we paid $7.5 million to the former AlmataBio stockholders upon the initial closing of the private placement investment, which closed on March 28, 2024. Further, a portion of the consideration for the AlmataBio Transaction includes development milestones to the former AlmataBio stockholders including $5.0 million due upon the first patient dosed in a Phase 2 trial in patients with hidradenitis suppurativa for abdakibart (AVTX-009) and $15.0 million due upon the first patient dosed in a Phase 3 trial for abdakibart (AVTX-009), both of which are payable in cash or our stock at the election of the former AlmataBio stockholders, subject to the terms and conditions of the definitive merger agreement. In October 2024, the first development milestone was met and we paid $5.0 million in cash.

Intellectual Property Overview

Our success depends in part on our ability to obtain and maintain proprietary protection for the technology and know-how upon which our product candidates are based, to operate without infringing the proprietary rights of third parties and to prevent third parties from infringing our proprietary rights.

We own a combination of in-licensed intellectual property rights, including patent applications, know-how and trademarks, and, in certain cases, regulatory exclusivity rights, if we receive marketing approval for abdakibart (AVTX-009) to develop and commercialize our product candidates covered by patents and patent applications. Our intellectual property portfolio includes patent applications with claims directed to compositions of matter, including compounds, pharmaceutical formulations of compounds, and methods of use of such compounds, or a combination of these claims. We also rely on trade secrets and proprietary know-how, including manufacturing and formulation know-how, as well as confidentiality agreements and other contractual protections, to protect aspects of our technology and product candidates that may not be patentable or that we elect not to patent. Depending upon the timing, duration and specifics of FDA approval of the use of a compound for a specific indication, some of our U.S. patents may be eligible for a limited patent term extension, also called marketing exclusivity, under U.S. patent term extension provisions including under the Drug Price Competition and Patent Term Restoration Act of 1984 and related statutory authority, and similar patent term extensions or supplementary protection may be available in other countries for particular patents in our portfolio including, where applicable, Supplementary Protection Certificates ("SPCs") in Europe (including the EU and the UK).

When possible, we plan to augment our portfolio of product candidates by focusing on the development of new biologics which have not previously received FDA approval. Upon approval by the FDA, new biologics are entitled to marketing exclusivity in the United States with respect to generic drug competition for a maximum period of five years from the date of FDA approval, even if the related patents have expired. Similarly, upon approval by the FDA, biologics are entitled to reference product exclusivity, also called regulatory exclusivity, for a period of twelve years from the date of FDA approval, even if the related patents have expired.

If we receive marketing approval for abdakibart (AVTX-009), we expect to receive biologics reference product exclusivity in the United States, which may provide twelve years of regulatory exclusivity in the United States from the date of FDA approval and a period of regulatory data protection, as well as a minimum of 9 years, and potentially up to 11 years based certain criteria as required, of regulatory exclusivity legislation in Europe , the scope and duration of which is jurisdiction-specific and may be subject to legislative or regulatory change.

As the composition of matter patent covering abdakibart (AVTX-009) expired in February 2026, we plan to primarily rely on biologics regulatory exclusivity for abdakibart (AVTX-009); however, the table below sets forth details of patent applications related to abdakibart (AVTX-009) that might provide additional protection that we consider material:

Jurisdiction	Owned/Licensed	Status	Expiration Date	Protection Type
United States Non-Provisional	Owned	Pending	2045	Methods of Treating HS
Worldwide (PCT)	Owned	Pending	2045	Methods of Treating HS
United States Non-Provisional	Owned	Pending	2045	Formulations
Worldwide (PCT)	Owned	Pending	2045	Formulations

Manufacturing

We do not have any manufacturing facilities. We currently utilize, and expect to continue to utilize third-party contract development and manufacturing organizations (CDMOs) to, among other things, supply and manufacture raw materials, components, parts and consumables, and to perform quality testing for our preclinical and clinical supply for all of our biologic product candidates. We currently rely on a single CDMO to manufacture clinical supply for abdakibart (AVTX-009). Further, we rely on and expect to continue to rely on such CDMOs to produce our biologic candidates in accordance with applicable regulations, including manufacturing activities performed in accordance with FDA's current good manufacturing practices ("cGMP") regulations, and similar regulations and standards in other jurisdictions. The manufacture of biological products is subject to extensive cGMP regulations, which impose various procedural and documentation requirements and also govern record keeping, production processes and controls, personnel and quality control.

Sales and Marketing

Given our stage of development as a company, we have limited resources dedicated to sales, distribution and marketing. To successfully commercialize any products that may result from our development programs, we will need to further develop sales and marketing capabilities, either on our own or with third parties in the respective jurisdictions where marketing approval has been obtained. We may retain or partner with third parties for commercialization rights and to develop sales and marketing capabilities. If we develop our own sales force, we may complement it with co-promotion agreements with partners in and outside of the United States.

Overall Competitive Climate and Regulatory Risks

Competition

We face, and will continue to face, intense competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, both in the United States and abroad. We compete, or will compete, with existing and new products being developed by our competitors. Some of these competitors are pursuing the development of pharmaceuticals that target the same diseases and conditions that our research and development programs target or might target. Some of these competitors also have greater resources and more experience than we do in research and development and marketing. Competitors may have a variety of drugs in development or awaiting FDA approval that could reach the market and become established before we have an approved product to sell. Our competitors may also develop alternative therapies that could limit the market for any approved drugs that we may develop. Many of our competitors are using technologies or methods different or similar to ours to identify and validate drug targets and to discover novel small compound drugs.

In particular, pharmaceutical and biotechnology companies that develop and/or market products targeting IL-1β or the indications we are pursuing, including HS, are likely to represent substantial competition.

As of the date of this report, and to our knowledge, there are two companies with approved anti-IL-1β antibodies (Novartis AG or "Novartis" and Changchun GeneScience Pharmaceuticals Co., Ltd. or "GenSci") and we are one of three additional companies with novel, non-biosimilar antibodies specifically targeting IL-1β in clinical development worldwide (Sunshine Guojian Pharmaceutical Co Ltd, or "Sunshine Guojian", and TavoTek), inclusive of all approved indications and indications in development. There are additional companies developing and/or marketing known or investigational therapeutic agents that target IL-1β and/or IL-1α through interactions with IL-1 receptors, engineered bispecific antibodies, or through adjacent mechanistic targets (such as IL-1RAP and NLRP3).

Worldwide, several companies currently market TNF alpha inhibitors (such as AbbVie Inc., or "AbbVie", and additional companies marketing biosimilars) and IL-17 inhibitors (such as Novartis and UCB) for HS. As of the date of this report, six additional companies have ongoing or completed phase 3 development programs in HS with IL-17 inhibitors (Moonlake Immunotherapies, Inc.), JAK inhibitors (Incyte Corporation, AbbVie), BTK inhibitors (Novartis), and dual IL-1α/β inhibitors (AbbVie). There are multiple additional companies pursuing phase 2, phase 1, and preclinical development programs in HS.

Competition in the inflammatory disease market is intense. We face competition from many large pharmaceutical companies. There are numerous other companies that have commercialized or are developing treatments for HS and inflammatory diseases that we will compete with, including AbbVie, Lilly, Merck, Novartis, Pfizer, Sanofi, Takeda, UCB and others. Many of our competitors and their collaborators may have significantly greater experience than we do in the following:

- identifying and validating targets;
- screening compounds against targets;
- preclinical and clinical trials of potential pharmaceutical products; and
- obtaining FDA and other regulatory clearances.

In addition, many of our competitors and their collaborators have substantially greater advantages in the following areas:

- capital resources;
- research and development resources;
- manufacturing capabilities; and
- sales and marketing resources.

Smaller companies might also prove to be significant competitors, particularly through proprietary research discoveries and collaborative arrangements with large pharmaceutical and established biotechnology companies.

Regulatory

There is no guarantee that our products will obtain regulatory approval by the United States Food and Drug Administration (the "FDA") or comparable foreign regulatory authorities. The FDA approval process is complex, time-consuming, and expensive. Prior to submitting a new drug application ("NDA") or biologics license application ("BLA"), the FDA approval process typically involves the following: preclinical laboratory and animal testing, submission of an Investigational New Drug ("IND") application, and human clinical trials to establish safety and efficacy. Human clinical trials typically include: Phase 1 studies to evaluate the safety and tolerability of the drug, generally in normal, healthy volunteers (although for biologics and certain serious or inflammatory diseases, first-in-human studies may be conducted in patients); Phase 2 studies to evaluate safety and efficacy, as well as appropriate doses; these studies are typically conducted in patient volunteers who suffer from the particular disease condition that the drug is designed to treat; and Phase 3 studies to evaluate the safety and efficacy of the product at specific doses in one or more larger pivotal trials.

As a biologics-focused company, our product candidates are subject to additional regulatory scrutiny, including requirements related to manufacturing process validation, product consistency, immunogenicity, and ongoing comparability assessments, and the FDA may require extensive chemistry, manufacturing and controls ("CMC") data both before and after approval. Because biologics are derived from living systems, changes to manufacturing processes, facilities or suppliers may require additional regulatory review or approval.

Upon submission of an NDA or BLA, the FDA reviews the application, which potentially involves an FDA advisory committee review, and typically inspects manufacturing facilities and clinical study sites. The FDA has substantial discretion in the approval process and may require additional clinical studies, new or modified endpoints, expanded safety data, or longer follow-up periods as a condition to approval, even if earlier trials produce favorable results. Even if the FDA approves a product, it may impose post-approval requirements, such as risk evaluation and mitigation strategies, post-marketing studies or enhanced pharmacovigilance obligations, or withdraw approval if safety or efficacy issues arise.

We are currently conducting clinical development programs, including Phase 2 clinical trials, and success in earlier-stage trials does not ensure that later-stage trials will be successful or that regulatory approval will be obtained. The FDA may determine that additional studies are required prior to advancing to later-stage trials or submitting an NDA or BLA.

The processes for obtaining marketing approvals in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources. Regulatory approval in foreign jurisdictions is generally independent of FDA approval and may require additional clinical data, different endpoints, or separate manufacturing inspections.

Regulatory authorities in the European Union, the United Kingdom and other jurisdictions may apply standards that differ from those of the FDA, and clinical trial data generated in one jurisdiction may not be accepted by regulatory authorities in another. Delays or failures in obtaining foreign regulatory approvals could adversely affect the timing and scope of any potential commercialization outside the United States.

Government Regulation and Product Approval

Government authorities in the United States and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export, pricing, and government contracting related to biological products such as those we are developing.

United States Government Regulation

In the United States, the FDA regulates biologics under the Federal Food, Drug, and Cosmetic Act ("FDCA"), the Public Health Service Act, and its implementing regulations. The process of obtaining marketing approvals and subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve a pending NDA or BLA, withdrawal of an approval, imposition of a clinical hold or study termination, issuance of Warning Letters or Untitled Letters, mandated modifications to promotional materials or issuance of corrective information, product recalls, consent decrees, corporate integrity agreements, deferred prosecution agreements, product seizures or detentions, refusal to allow product import or export, total or partial suspension, restriction, or imposition of other requirements relating to production or distribution, injunctions, consent decrees, fines, debarment from government contracts and refusal of future orders under existing contracts, exclusion from participation in federal and state healthcare programs, FDA debarment, restitution, disgorgement or civil or criminal penalties, including fines and imprisonment (and, in certain cases, the imposition of compliance obligations pursuant to settlements or similar arrangements).

Clinical Development in the U.S.

Obtaining FDA marketing approval for a new product may take many years and require the expenditure of substantial financial resources. For the FDA to determine that a product is safe and effective for the proposed indication, the product must first undergo testing in animals (nonclinical studies). The data generated from nonclinical studies is used to support the filing of an Investigational New Drug application ("IND"), which must become effective before human clinical studies may begin.

Clinical development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with good clinical practice ("GCP") requirements, which include the requirement that all patients provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative, and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

A sponsor that wishes to conduct a clinical trial outside of the U.S. may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of a BLA. The FDA will accept a well-designed and well-conducted foreign clinical study not conducted under an IND if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials are generally conducted in three sequential phases, which may overlap or be combined:

- Phase 1: Studies in a small number of subjects with the primary purpose of assessing the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate, generally in normal, healthy volunteers but sometimes for certain biologics and serious diseases, in patients;
- Phase 2: Studies generally designed to evaluate proof of concept and determine the dosing regimen(s) for subsequent investigations, and further assess safety and PK/PD in patients who have the particular disease condition that the drug is designed to treat. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials; and
- Phase 3: Studies in an expanded patient population to provide statistically significant evidence of clinical efficacy and to further test for safety, generally conducted at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of an investigational product and to provide an adequate basis for labeling and product approval.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of a BLA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the trial.

Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry, manufacturing and controls ("CMC") for the investigational product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements and, as applicable, demonstrate process consistency and comparability as manufacturing scales.

Under the Pediatric Research Equity Act ("PREA"), as amended, a BLA or supplement to a BLA must contain data to assess the safety and efficacy of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted. A sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan ("PSP") within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs.

The preparation of an NDA or BLA requires the expenditure of substantial funds and the commitment of substantial resources. Additionally, at the time of an NDA or BLA submission a user fee is required to be paid unless the product has orphan drug designation ("ODD") or another waiver or reduction applies. The FDA conducts a preliminary administrative review upon receipt of the NDA or BLA submission and decides whether to accept the NDA or BLA submission. If the application is not accepted for review by the FDA through a "refuse-to-file" determination, the Sponsor of the application must resolve the deficiencies and resubmit the application, restarting the review clock.

After evaluating the NDA or BLA and all related information, including if there is an advisory committee recommendation, and inspection reports regarding the manufacturing or laboratory facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter ("CRL"). A CRL generally contains a statement of specific conditions that must be met to secure final approval of the NDA or BLA and may require additional clinical or nonclinical studies, or other information. Even with submission of this additional information, the FDA may decide that the NDA or BLA does not satisfy the regulatory criteria for approval. The FDA will not approve an application until issues identified in any complete response letters have been addressed. Even if such data and information are submitted, the FDA may decide that the application does not satisfy the criteria for approval. Failure to respond to a complete response letter may be considered by the FDA as a request to withdraw the application.

If and when those conditions have been met to the FDA's satisfaction, the FDA may issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a new product, the approval may be limited to specific disease states, patient populations and dosages, and the indications for use may otherwise be limited. The FDA may also require that contraindications, warnings, or precautions be included in the product labeling. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, certain manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

FDA Review Process

Following completion of clinical trials, the data are analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of a BLA, along with proposed CMC and manufacturing information to ensure product quality and other relevant data. The BLA is a request for approval to market the biologic for one or more specified indications and must contain preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, efficacy,, purity and potency for a biologic candidate. The application may include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a biologic may be marketed in the U.S.

Under the Prescription Drug User Fee Act ("PDUFA") as amended, each BLA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all submitted BLAs before it accepts them for filing, and may request additional information rather than accepting the BLA for filing. The FDA must make a decision on accepting a BLA for filing within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth review of the BLA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 months from the filing date in which to complete its initial review of an original BLA and respond to the applicant, and six months from the filing date of an original BLA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs, and the review process is often extended by FDA requests for additional information or clarification.

Before approving a BLA, the FDA generally will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. In certain circumstances, the FDA may require a Risk Evaluation and Mitigation Strategy ("REMS") to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS, and the FDA will not approve the BLA without an approved REMS. A REMS 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.

After the FDA evaluates a BLA, it will issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. A complete response letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A complete response letter usually describes all of the specific deficiencies in the BLA identified by the FDA. The complete response letter may require additional clinical data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the BLA does not satisfy the criteria for approval.

Data obtained from a development program is not always conclusive and may be susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing any approved product candidates. The FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial opportunity of the approved product.

FDA Post-Approval Considerations

Drugs manufactured or distributed pursuant to FDA approval are subject to continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, manufacturing, periodic reporting, product sampling and distribution, advertising and promotion, and reporting of adverse experiences with the product and drug shortages. During the approval process, the FDA and the sponsor may agree that specific studies or clinical trials should be conducted as post-marketing commitments or post-marketing requirements as a condition of approval of a BLA. The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product becomes available in the market. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA 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.

After approval, many changes to the approved product, such as manufacturing changes and adding new indications or other labeling claims, are subject to FDA review and approval. There are also annual user fee requirements for marketed products and application fees for supplemental applications with clinical data. Additionally, the FDA strictly regulates the labeling, advertising and promotion of products under an approved BLA. The FDA and other agencies enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that improperly markets or promotes off-label uses may be subject to significant liability, including criminal and civil penalties under the FDCA and False Claims Act, exclusion from participation in federal healthcare programs, debarment from government contracts, refusal of future orders under existing contracts and mandatory compliance programs under corporate integrity agreements or deferred prosecution agreements.

Coverage and Reimbursement

The success of our product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors. We cannot be sure that coverage and reimbursement will be available for our product candidates, nor can we accurately estimate the potential revenue from them. Similarly, we cannot assure that coverage and reimbursement will be available for any product that we may develop.

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. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates, once approved. Patients are unlikely to use our product candidates, once approved, unless coverage is provided and reimbursement is adequate to cover a significant portion of their cost.

There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives.

Moreover, increasing efforts by governmental and other 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. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether existing regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals or clearances of our product candidates, if any, may be.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Other Healthcare Laws and Compliance Requirements

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 that 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 authorization. Arrangements with third-party payors and customers can expose pharmaceutical manufactures to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act (FCA) which may constrain the business or financial arrangements and relationships through which companies research, sell, market and distribute pharmaceutical products. In addition, transparency laws and patient privacy laws can apply to the activities of pharmaceutical manufactures.

The applicable federal, state and foreign healthcare laws and regulations that can affect a pharmaceutical company's operations include without limitation:

- The federal Anti-Kickback Statute, which prohibits, among other things, 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, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under the Medicare and Medicaid programs, or other federal healthcare programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. 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 FCA or federal civil monetary penalties. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but such exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection;

- The federal civil and criminal false claims laws, including the FCA, and civil monetary penalty laws, which prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government or knowingly making, using or causing to be made or used a false record or statement, including providing inaccurate billing or coding information to customers or promoting a product off-label, material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the federal government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their respective implementing regulations, which impose, among other things, specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates as well as their covered subcontractors. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- The federal legislation commonly referred to as the Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which requires certain 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 CMS, information related to payments or other transfers of value made to physicians, other licensed care professionals and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- Federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;

- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor.

Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. State and foreign laws, including for example the European Union General Data Protection Regulation, which became effective May 2018 also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations with respect to certain laws. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect our business in an adverse way. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. Ensuring our business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

The failure to comply with any of these laws or regulatory requirements subjects companies to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical company to incur significant legal expenses and divert management's attention from the operation of the business.

Healthcare Reform and Other Regulatory Changes

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare.

For example, in 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 in the United States. The ACA includes measures that have significantly changed, and are expected to continue to significantly change, the way healthcare is financed by both governmental and private insurers. The ACA contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and changes to fraud and abuse laws. Among the provisions of the ACA of greatest importance to the pharmaceutical industry are that the ACA:

- subjects biological products to potential competition by biosimilars;
- made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability; and
- extended a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted include the following:

- The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. Subsequent legislation extended the 2% reduction which remains in effect through 2031.

- On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.
- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.
- On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024. These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.
- Further, on May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.
- The Inflation Reduction Act of 2022 (IRA) includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. Under the One Big Beautiful Bill Act of 2025, this restriction was eliminated; and effective for the 2028 initial price applicability year, all orphan drugs, regardless of the number of orphan drug designations or indications, are exempt from the Medicare drug price negotiation program. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. Although the effects of the IRA on our business and the healthcare industry in general are not yet known, we are taking into consideration the potential impact of the IRA on our development and commercialization activities. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

The costs of prescription drugs and biological products have also been the subject of considerable discussion in the United States. At a federal level, President Trump reversed some of President Biden's executive orders including rescinding Executive Order 14087 entitled "Lowering Prescription Drug Costs for Americans." President Trump may issue new executive orders designed to impact prescription product pricing. A number of these and other proposed measures may require authorization through additional legislation to become effective. Congress and the Trump administration have indicated that they will continue to seek new legislative measures to control prescription product costs.

On April 15, 2025, the Trump Administration published Executive Order 14273, "Lowering Drug Prices by Once Again Putting Americans First," which generally directs the federal government to take measures to reduce drug prices, including eliminating the so-called "pill penalty" under the Inflation Reduction Act that creates a distinction between small molecule and large molecule products for purposes of determining when a drug may be eligible for drug price negotiation. On May 12, 2025, the Trump Administration published Executive Order 14297, "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients" which generally, among other things, directs the federal government to establish and communicate most-favored-nation ("MFN") price targets to pharmaceutical manufacturers to bring prices for American patients in line with comparably developed nations. Further, the Executive Order directs the federal government to support regulatory paths to allow direct-to-patient sales for companies that meet these targets. It also states that the Administration will take additional aggressive action (for example, examining whether marketing approvals should be modified or rescinded or opening the door for individual drug importation waivers) should manufacturers fail to offer American consumers the MFN lowest price or otherwise meet the Administration's pricing objectives. It also directs the Secretary of Commerce and the U.S. Trade Representative to "take all necessary and appropriate action to ensure foreign countries are not engaged in any act, policy, or practice that may be unreasonable or discriminatory or that may impair United States national security . . . including by suppressing the price of pharmaceutical products below fair market value in foreign countries." Notably, a similar "Most Favored Nation" pricing rule enacted under the first Trump Administration was subject to an injunction resulting from judicial challenges to the rule, which was formally rescinded by the former Biden Administration in August 2021.

We cannot predict whether, when, or in what form the current Executive Orders or related agency actions will be implemented, challenged, modified, delayed or enjoined.

On December 19, 2025, CMS released two proposed rules that would incorporate MFN pricing principles into federal reimbursement for prescription drugs. The first proposal, the Global Benchmark for Efficient Drug Pricing Model ("GLOBE") for Medicare Part B, would require manufacturers of specified single source drugs and sole source biologics to pay incremental rebates based on international benchmark prices, with participation triggered for products meeting CMS's spending and eligibility criteria. The second proposal, the Guarding U.S. Medicare Against Rising Drug Costs ("GUARD") model for Medicare Part D, would similarly mandate manufacturer rebates for qualifying sole source drugs where the Medicare net price exceeds an MFN benchmark derived from international reference pricing methodologies. As proposed, GLOBE would begin a five year performance period on October 1, 2026 and GUARD would begin its performance period in 2027. These proposals will likely be subject to legal challenges that could delay their implementation or modify their impact on manufacturer pricing and revenue. Additionally, in November 2025, CMS introduced the GENErating cost Reductions for U.S. Medicaid ("GENEROUS") Model, a voluntary MFN framework for manufacturers participating in the Medicaid Drug Rebate Program. Although it is voluntary, the GENEROUS Model could also impact the drug pricing landscape for manufacturers.

In addition, at the state level, legislatures have increasingly passed legislation and implemented regulations similar to those under consideration at the federal level, as well as laws designed to control pharmaceutical and biotherapeutic product pricing, including restrictions on pricing or reimbursement at the state government level, limitations on discounts to patients, marketing cost disclosure and transparency measures, restrictions or other limitations on patient assistance, and, in some cases, policies to encourage importation from other countries (subject to federal approval) and bulk purchasing. Certain states are also pursuing cost containment efforts through Prescription Drug Affordability Boards ("PDABs") and similar entities. While many PDABs have been granted authority to promote drug price transparency and reporting, some states have granted PDABs more expansive authority, including to set Upper Payment Limits (UPLs) on select, high price drugs. The adoption and implementation of UPLs may put downward pressure on drug prices and impact our company's future revenues.

Exclusivity and Approval of Competing Products

Approval of Biosimilars and Biologic Exclusivity

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") created an abbreviated approval pathway for biological products that are demonstrated to be "biosimilar" or "interchangeable" with an FDA-licensed reference biological product. Biosimilarity is established by demonstrating that there are no clinically meaningful differences between the biological product and its reference product in terms of safety, purity, and potency. This determination is typically based on analytical studies, animal studies, and in some cases, clinical studies. Interchangeability requires that a product is biosimilar to the reference product and must further show that it is expected to produce the same clinical results in any given patient. For products administered multiple times, the reference biologic and the interchangeable biologic must be able to be switched or alternated without increasing safety risks or compromising efficacy compared to exclusive use of the reference biologic.

A product designated as biosimilar or interchangeable to an FDA-approved reference biological product may rely on the FDA's prior determination of safety and effectiveness for that reference product. This reliance can reduce both the cost and time required to obtain market approval. However, due to the larger and more complex structures of biological products and the intricate manufacturing processes involved, the biosimilar pathway remains challenging to implement.

Under the BPCIA, an application for a biosimilar cannot be submitted to the FDA until four years after the reference product was first licensed. Furthermore, the FDA cannot approve a biosimilar until 12 years after the reference product's initial approval. During this 12-year exclusivity period, a competing product may still be marketed if the FDA approves a full BLA containing the applicant's own preclinical and clinical trial data demonstrating safety, purity, and potency. Additionally, the BPCIA provides certain exclusivity periods for biosimilars designated as interchangeable products. State pharmacy laws govern whether FDA-approved interchangeable products can be readily substituted for the reference product .

Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent regulatory and marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent exclusivity period described above. This six-month exclusivity may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding biologic and drug development, approval and commercialization. The approval process varies by country and can involve additional product testing and additional administrative review periods.

The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. The processes for obtaining marketing approvals in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

European Union Drug Approval Process

To obtain a marketing authorization for a medicinal product, including a biologic,in the European Union, we may submit marketing authorization applications ("MAAs") either under the so-called centralized, decentralized, mutual recognition or national authorization procedures.

Centralized procedure

The centralized procedure provides for the grant of a single marketing authorization following a favorable opinion by the European Medicines Agency ("EMA") that is valid in all European Union member states, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for medicines produced by specified biotechnological processes, products designated as orphan medicinal products, and products with a new active substance indicated for the treatment of specified diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions and viral diseases. The centralized procedure is optional for products that represent a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public health.

National authorization procedures

There are also three other possible routes to authorize medicinal products in several European Union countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure.

- **National authorization procedure.** This procedure involves submitting an MAA to an individual EU country's competent authority for approval. Each EU Member State has its own national authorization procedures.

- **Decentralized procedure.** Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one European Union country of medicinal products that have not yet been authorized in any European Union country and that do not fall within the mandatory scope of the centralized procedure.

- **Mutual recognition procedure.** In the mutual recognition procedure, a medicine is first authorized in one European Union Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other European Union countries in a procedure whereby the countries agree to recognize the validity of the original, national marketing authorization.

In the European Union, new products authorized for marketing (i.e., reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a follow-on marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful follow-on applicant from commercializing its product in the EU until ten years have elapsed from the initial authorization of the reference product in the EU. The ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Employees and Human Capital Management

As of December 31, 2025, we had 33 employees, all of whom were full-time. 18 of our employees are primarily engaged in research and development activities. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

We believe that our future success largely depends upon our ability to scale and to attract and retain highly skilled and qualified personnel. We believe that we provide our employees with competitive salaries and bonuses, opportunities for equity ownership, and an employment package that promotes well-being across all aspects of their lives, including health care, retirement planning and paid time off. We believe that much of our success is rooted in the variety of backgrounds represented in our teams and our commitment to inclusion. We focus on extending our inclusion initiatives across our entire workforce.

Corporate Information

We were incorporated in Delaware in 2011 and commenced operations in the second quarter of 2011. We completed our initial public offering in October 2015. Our principal executive offices are located at 1500 Liberty Ridge Drive, Suite 321, Wayne, PA 19087, and our phone number is (410) 522-8707. Our website address is www.avalotx.com. The information on, or that can be accessed through, our website is not part of this report. We have included our website address in this report solely as an inactive textual reference.

Available Information

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act"), are available free of charge on our website at www.avalotx.com as soon as reasonably practicable after electronically filing or furnishing such material to the Securities and Exchange Commission. The Securities and Exchange Commission maintains a website (www.sec.gov) that includes our reports, proxy statements and other information.

Item 1A. Risk Factors.

You should consider carefully the following information about the risks described below, together with the other information contained in this Annual Report on Form 10-K and in our other public filings, in evaluating our business. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price and value of our securities would likely decline. Additional risks or uncertainties not presently known to us or that we currently deem immaterial may also harm our business. Moreover, some of the factors, events and contingencies discussed below may have occurred in the past, but the disclosures below are not representations as to whether or not the factors, events or contingencies have occurred in the past and instead reflect our beliefs and opinions as to the factors, events, or contingencies that could materially and adversely affect us in the future.

Risks Related to Our Financial Position and Capital Needs

We expect to require additional capital in the future to continue to fund our operations and to finance the further advancement of our product candidates, which might not be available to us on acceptable terms, or at all. Failure to obtain any necessary capital could force us to delay, limit or terminate our product development efforts or significantly curtail or cease our operations altogether.

As a research and development company, our operations have consumed substantial amounts of cash since inception. Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance our current product candidates through or into clinical trials and prepare for later-stage development activities, including manufacturing scale-up, regulatory engagement, and commercialization planning. Circumstances may cause us to consume or require capital more rapidly than we currently anticipate. Historically, our capital constraints have required us to prioritize certain development programs over others, including deferring, out-licensing or discontinuing certain candidates, and we may be required to do so again in the future. We will need to raise additional funds or otherwise obtain funding through collaborations to complete the development of abdakibart (AVTX-009) and any other product candidates and to continue our operations.

We plan to finance our operations through a combination of equity offerings, debt financings, collaborations, licensing arrangements and other similar arrangements. We do not have any committed sources of external financing. Our ability to raise additional funds may be adversely impacted by global economic conditions, disruptions to, and volatility in, the credit and financial markets in the United States and worldwide, and diminished liquidity and credit availability, and biotechnology-specific market conditions, including reduced investor appetite for clinical-stage companies. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. If we are unable to raise capital when needed or on attractive terms, we would be forced to:

- Significantly delay, scale back or discontinue the development or commercialization of abdakibart (AVTX-009) or other product candidates or cease operations altogether;
- Seek strategic alliances for research and development programs at an earlier stage than we would otherwise desire or on terms less favorable than might otherwise be available; or
- Relinquish, or license on unfavorable terms, our rights to technologies or any future product candidates that we otherwise would seek to develop or commercialize ourselves.

At December 31, 2025, we had $98.3 million in cash and cash equivalents and short-term investments and $12.9 million in current liabilities. As of the date of this Report, we believe we have sufficient funds to finance our continuing operations into 2028 to further advance abdakibart (AVTX-009) and other product candidates. This estimate is based on assumptions regarding our operating plan, clinical timelines, and expenditures that may prove to be inaccurate. We could use our capital resources sooner than we currently expect due to unanticipated delays, cost overruns, changes in regulatory strategy, or other factors. We will likely need to raise additional funds prior to any phase 3 development and/or indication expansion. Additionally, if there are significant unexpected delays and/or cost overruns in our current Phase 2 LOTUS trial, or other negative deviations from cash forecast, we might require additional funds prior to the Phase 2 LOTUS trial read-out.

We may never achieve or sustain profitability.

To become and remain profitable, we must succeed in developing, obtaining regulatory approvals for, and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing clinical trials and preclinical studies and obtaining regulatory approval for one or more of our current and future product candidates, and manufacturing, marketing, and selling any products for which we may obtain regulatory approval. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable may have an adverse effect on the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidates, achieve our strategic objectives or even continue our operations.

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

Additional fundraising efforts may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we do not have any committed external sources of funding and cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all.

We may need to seek additional funds sooner than anticipated through public or private equity offerings, debt financings, collaborations, licensing agreements, or other sources. Such financing could dilute our stockholders, and failure to secure adequate funding may limit our operational activities.

If we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of such financing could include liquidation preference, anti-dilution provisions, or other rights that may negatively impact stockholders. Debt financing could impose restrictive covenants, increase fixed payment obligations, or introduce other constraints that could affect our business operations.

If we secure additional funds through upfront or milestone payment as part of future collaborations with third parties, we may be required to relinquish valuable rights to abdakibart (AVTX-009) or grant licenses under terms that are not favorable to us. Our ability to raise additional capital may be negatively affected by macro events, such as worsening global economic conditions, disruptions to financial markets, and volatility in credit markets in the United States and worldwide, as well as biotechnology specific industry events and trends.

We might never progress to the point where we have commercially successful product sales or other revenue sufficient to sustain operations. Accordingly, we may seek to raise needed funds through public or private equity offerings, debt financings, credit facilities, partnering or other corporate collaborations and licensing arrangements. If adequate funds are not available or are not available on acceptable terms, our ability to fund our operations, take advantage of opportunities, develop products and technologies, and otherwise respond to competitive pressures could be significantly delayed or limited, and we might need to downsize or halt our operations.

We have incurred significant net losses in most periods since our inception and we expect to continue to incur net losses for the foreseeable future.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate an adequate effect or acceptable safety profile, gain marketing approval and become commercially viable. We are a clinical-stage biotechnology company with a limited operating history upon which you can evaluate our business and prospects. We commenced operations in 2011, have no products approved for commercial sale and have not generated any revenue from product sales. Since our inception, we have devoted substantially all our resources to building our organization, including an acquisition, raising capital, researching, discovering and developing potential drug candidates, establishing and maintaining our intellectual property portfolio, conducting preclinical studies and clinical trials, organizing and staffing our company, business planning and providing general and administrative support for these operations. We have not yet demonstrated the ability to successfully obtain regulatory approvals, manufacture products at commercial scale, establish reliable third-party manufacturing capabilities, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products.

Historically, we have financed our operations primarily through public and private equity offerings. We incurred a net loss of $78.3 million for the year ended December 31, 2025. As of December 31, 2025, we had an accumulated deficit of $448.5 million. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development program and from general and administrative costs associated with supporting our operations. We expect that our existing cash and cash equivalents and short-term investments will allow us to advance the clinical development of abdakibart (AVTX-009) and other product candidates, and we expect that the remainder will be utilized to fund other research and development activities as well as working capital and other general corporate needs. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner or differently than we currently expect.

Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, including but not limited to including clinical trial delays or failures, changes in regulatory requirements, manufacturing challenges, strategic decisions, or competitive developments and we may need to seek additional funds sooner than planned. Our existing cash and cash equivalents and short-term investments may not be sufficient to complete development of any of our current or future product candidates. We will require substantial capital in order to advance any of our current and future product candidates through clinical trials, regulatory approval and commercialization.

Our future funding requirements, both short and long term, will depend on many factors, including:

- The initiation, progress, timing, costs and results of preclinical and clinical studies for abdakibart (AVTX-009) and any future product candidates we may develop;
- The level of research and development investment required to develop product candidates through clinical development and prepare for later stage trials;
- The rate and level of patient recruitment into clinical trials;
- The timing and amount of milestone payments we are required to make under license agreements;
- Changes in product development plans needed to address any difficulties that may arise in manufacturing, preclinical activities, clinical trials, regulatory interactions, or commercialization;
- The outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and other regulatory authorities, including the potential for such authorities to require that we perform more studies than currently expected;
- The initiation and completion of all required safety and efficacy studies necessary for obtaining regulatory approval in the U.S. including additional clinical trials or studies beyond those currently planned to support abdakibart (AVTX-009)'s approval and commercialization;
- Providing sufficient evidence to the FDA, and other global regulatory bodies demonstrating the safety, efficacy, and an acceptable risk-benefit profile of abdakibart (AVTX-009) or any future other product candidates;
- Our ability to promptly submit and secure clearance of IND applications for our programs to initiate planned or future clinical trials;
- Effectively monitor and manage the occurrence, duration, and severity of any potential side effects or safety concerns associated with our product candidates, if any arise;
- Securing timely marketing approvals from the FDA, and other relevant regulatory authorities;
- The cost to establish, maintain, expand and defend the scope of our intellectual property portfolio and patent claims, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing any patents or other intellectual property rights;
- Competitive dynamics, including the timing of competitor data readouts, approvals, and commercial launches;
- The cost and timing of selecting, auditing and potentially validating a manufacturing site for commercial-scale manufacturing;
- The cost of future commercialization activities including, developing our sales, marketing, manufacturing and distribution capabilities to accommodate any of our product candidates for which we receive marketing approval and that we determine to commercialize ourselves or in collaboration with our partners;
- Market acceptance of any approved product candidates;
- The effect of competing product and market developments;
- The ability and willingness to enter into new agreements with strategic partners, and the terms of these agreements; and
- The costs of acquiring, licensing or investing in additional businesses, products, product candidates and technologies.

We expect to continue to incur losses in the future and we might never achieve profitability on an annual basis. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Our future profitability will depend, in part, on the rate of future growth of our expenses as we develop our product candidates and the successful completion of clinical development and regulatory approval, and our ability to generate revenues from any approved products. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Risks associated with short-term liquid investments.

At December 31, 2025, we had $98.3 million in cash and cash equivalents and short-term investments. We historically have invested our cash in money market funds and investment-grade marketable securities such as corporate and government bonds, commercial paper, asset-backed securities, U.S. treasury securities, money market funds, and other cash equivalents, consistent with our investment policy. These investments are intended to preserve principal value and maintain a high degree of liquidity while providing current income. However, these instruments are subject to general credit, liquidity, market and interest rate risks. We may realize losses in the fair value of these investments, which could include a complete loss of these investments, which would have a negative effect on our consolidated financial statements. In extreme market conditions, such losses could be material.

In addition, should our investments cease paying or reduce the amount of interest paid to us, our interest income would decrease. Interest rate fluctuations can negatively impact the returns on our fixed-income investments, particularly during periods of rising interest rates.

Further, these types of investments are not insured against loss of principal, and cash and cash equivalents and short-term investments held in deposit accounts bear the risk of bank failure to the extent balances exceed applicable government insurance limits**.** There is no guarantee that investments in these assets will be redeemable at par value. Once invested, if we cannot liquidate our investments, or redeem them at par, we could incur losses and experience liquidity issues. A decline in the value of our investments or a delay or suspension of our right to redeem may have a material adverse effect on our results of operations or financial condition.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We have a significant amount of gross net operating losses ("NOLs") for federal and state purposes. The Company has accumulated $3.4 million of NOLs through the end of 2017, which will begin to expire in 2031. Unused NOLs for the current tax year and prior tax years will carry forward to offset future taxable income, if any, until such unused losses expire. Unused NOLs generated after December 31, 2017 of $255.0 million, will not expire and may be carried forward indefinitely, but will be only deductible to the extent of 80% of current year taxable income in any given year. In addition, both the deductibility of current and future unused NOL carryovers may be subject to limitation under Sections 382 and 383 of the Internal Revenue Code ("IRC"). Sections 382 and 383 of the IRC subject the future utilization of NOLs and certain other tax attributes, such as research and experimental tax credits, to an annual limitation in the event of certain ownership changes. In general, an "ownership change" is defined as a greater than 50% change (by value) in equity ownership over a three-year period. As of December 31, 2025, the Company had various research tax credits of $7.7 million that will begin to expire in 2038. If we experience an ownership change, or if we do not generate sufficient taxable income before the expiration of these attributes, some or all of our NOLs or tax credits could expire unused. To the extent there is a limitation, there could be a reduction in the $8.4 million deferred tax asset related to Federal loss carryforwards and tax credits that may have expired unutilized with an offsetting reduction in the valuation allowance.

Our operating results fluctuate from quarter to quarter and year to year, making future operating results difficult to predict.

Our quarterly and annual operating results historically have fluctuated and are likely to continue to fluctuate depending on several factors, many of which are beyond our control, including but not limited to the timing and outcome of clinical trials, regulatory interactions, financing activities, changes in operating plans, and macroeconomic or industry conditions. Accordingly, our quarterly and annual results are difficult to predict prior to the end of the quarter or year, and we may be unable to confirm or adjust expectations with respect to our operating results for a particular period until that period has closed. In addition, period-to-period comparisons of our operating results may not be meaningful due to the episodic nature of clinical development activities. In the event we provide cash projections or other guidance, any failure to meet such targets or failure to meet the expectations of analysts could adversely impact the market price of our securities. Therefore, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

We have no approved commercial products.

With no commercial products, our operations are not expected to produce revenues for the foreseeable future, or at all, which might harm our ability to obtain additional financing and might require us to reduce or discontinue our operations.

Our ability to generate revenue in the future will depend on developing and commercializing our current and future product candidates. Identifying, developing, obtaining regulatory approval and commercializing product candidates are prone to the risks of failure inherent in clinical development. Developing product candidates is expensive, and we expect to spend substantial amounts as we fund our product development. We cannot provide any assurance that we will be able to successfully advance any product candidate through the development process or successfully commercialize any product candidate, or that any such product candidate will be widely accepted in the marketplace or be more effective than other commercially available alternatives. Any failure to develop or commercialize a product candidate in our current clinical pipeline could require us to raise additional financing.

Risks Related to Development of Our Product Candidates

We are substantially dependent on the success of abdakibart (AVTX-009), and our ongoing and anticipated clinical trials of abdakibart (AVTX-009) may not be successful.

We acquired abdakibart (AVTX-009) in March 2024 and have focused our resources on abdakibart (AVTX-009) thereby increasing our exposure to risks associated with a single lead product candidate. Our future success, including financial condition and results of operations, relies heavily on our ability to successfully develop abdakibart (AVTX-009) for marketing approval and eventual commercialization.

We are dedicating the majority of our efforts and financial resources to the research and development of abdakibart (AVTX-009). In October 2024 we announced the first patient enrolled in our global Phase 2 LOTUS clinical trial and in October 2025 we announced that we completed enrollment.

Abdakibart (AVTX-009) will require further clinical development, generation and assessment of clinical and preclinical data, manufacturing activities, regulatory approval in multiple jurisdictions, substantial investment, additional scale, and significant marketing efforts before we can generate any revenue from product sales. We are not allowed to market or promote abdakibart (AVTX-009) until we receive marketing approval from the FDA and other comparable foreign regulatory authorities, and we may never obtain such approvals.

The success of abdakibart (AVTX-009) will depend on various factors, many of which are beyond our control. These include aspects of clinical development, the regulatory submission process, potential challenges to our intellectual property rights, and the manufacturing, marketing, distribution, and sales activities of any third parties with whom we may collaborate in the future. It could take years until abdakibart (AVTX-009) may receive marketing approval, and we may never obtain such marketing approval. Moreover, we cannot guarantee that we will ever generate revenue from the sale of abdakibart (AVTX-009), even if it receives regulatory approval. If we are unable to successfully commercialize abdakibart (AVTX-009), or if there are significant delays in doing so, our business will be materially impacted.

Any setback for or failure of abdakibart (AVTX-009) during its clinical development could cause material delays in and costs to its further development and commercialization. Any such delays or costs could have a material adverse effect on our financial condition and results of operations and could require us to raise more capital, turn to third-party collaborators to continue the development of abdakibart (AVTX-009) or cease operations. In addition, our focus on abdakibart (AVTX-009) may negatively impact the planned development of our other product candidates. Drug development is unpredictable and we could encounter toxicity, safety, adverse reactions or other concerns with abdakibart (AVTX-009) as we continue its development. There can be no assurances that we will successfully develop abdakibart (AVTX-009).

Interim, "topline," and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. Such data are inherently preliminary and should not be relied upon as definitive or predictive of final results.

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which is based on an initial analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. There can be no assurance that the final topline data from our trials will be consistent with such results or otherwise viewed as positive. We also may make assumptions, estimations, calculations and conclusions as part of our analyses of preliminary or topline data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary 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.

Topline data also remain subject to audit and verification procedures including data cleaning, source verification, and protocol-specified analyses, that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete, including data from of our clinical trials, 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 or as patients from our clinical trials continue other treatments for their diseases. Early trends observed in interim analyses may not persist through trial completion. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

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 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 material or otherwise appropriate information to include in our disclosure.

If the interim, topline, 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, our product candidates may be harmed, which could harm our business, results of operations, prospects or financial condition.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining required approvals from regulatory authorities for the sale of product candidates, we alone, or with a partner, must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive and difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early clinical trials may not predict the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. Our product candidates will require additional clinical and preclinical development, management of clinical, preclinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply on our own or from a third party, expansion of our commercial organization, and substantial investment and significant marketing efforts before we could generate any revenues from sales of any of those product candidates approved for marketing.

We cannot be certain whether the clinical trials we or our partners may conduct will demonstrate adequate efficacy and safety data to support regulatory approval that would enable us to market any of our product candidates in any particular country. We also cannot be certain whether the efficacy and safety profile shown in clinical trials of any of our product candidates will be regarded by investors as competitive relative to marketed products and/or product candidates in development by third parties. If later stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates would be adversely impacted, which could cause a sharp decline in our stock price and materially impair our ability to continue our operations. If clinical trials do not produce sufficiently favorable results, our ability to raise capital to fund our operations and complete the development and commercialization of our product candidates could be adversely impacted.

Our product candidates that we intend to commercialize are in early to mid-stages of development. If we do not successfully complete nonclinical testing and clinical development of our product candidates or experience delays in doing so, our business may be materially harmed. Our focus and reliance on abdakibart (AVTX-009) increases the risk of such exposure.

We have invested significant efforts and financial resources in the identification and preclinical and clinical development of product candidates, including abdakibart (AVTX-009). Our ability to generate significant product revenues will depend on our ability to advance our clinical product candidates toward approval and our preclinical product candidates into clinical development. The outcome of preclinical studies and earlier clinical trials might not predict the success of future clinical trials. Preclinical data and clinical trial data may be susceptible to varying interpretations and analyses, and many product candidates that performed satisfactorily in preclinical studies and early clinical trials have nonetheless failed in later clinical development.

If we experience delays in clinical testing, we will be delayed in obtaining regulatory approvals and commercializing our product candidates, our costs may increase and our business may be harmed.

We may experience delays in obtaining or maintaining the FDA's authorization to initiate clinical trials under future INDs and to complete ongoing clinical studies of our product candidates due to a variety of reasons. Our product development costs will increase if we experience delays in clinical testing. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may harm our business, results of operations and prospects.

Factors which may result in a delay or unsuccessful completion of clinical development include:

- Delays in or failure to obtain authorization from the FDA, other regulatory authorities or institutional review boards ("IRBs") or ethics committees ("ECs") to commence or amend a clinical trial;
- Delays in reaching alignment with the FDA or other regulatory authorities regarding requisite trial design or endpoints sufficient to establish a clinically meaningful benefit of our product candidates, given there might not be well-established development paths and outcomes in the indications we pursue;
- Imposition of a clinical hold or trial termination by regulatory authorities or us for any reason, including following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities or a decision by the FDA, other regulatory authorities, IRBs, ECs or us, or recommendation by a data safety monitoring board;
- Delays in reaching agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites, the terms of which may vary significantly among different CROs and clinical trial sites;
- Deviations from the trial protocol by clinical trial sites and investigators, or failure to conduct the trial in accordance with regulatory requirements;
- Failure of our third parties, such as CROs, to satisfy their contractual duties or meet expected deadlines;

- Delays in the importation and manufacture of clinical supply;
- Delays in the testing, validation and delivery of the clinical supply of the product candidates to the clinical sites;
- For clinical trials in selected subject populations, delays in identification and auditing of central or other laboratories and the transfer and validation of assays or tests to be used to identify eligible subjects;
- Delays in recruiting eligible subjects to participate in a trial;
- Delays in having subjects complete participation in a trial or return for post-treatment follow-up;
- Delays caused by subjects dropping out of a trial due to side effects, disease progression, or other reasons;
- Delays in adding new investigators and clinical trial sites;
- Delays resulting from national or global health or geopolitical situations, including military conflict, trade barriers, or governmental budget dynamics;
- Withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;
- Changes in government regulations or administrative actions; or
- Lack of adequate funding to continue or complete the clinical trials.

Any inability by us or our partners to complete clinical development in a timely manner could result in additional costs to us relating to product development and obtaining marketing approval and impair our ability to generate product revenues and commercialization and sales milestone payments and royalties on product sales.

If we are unable to enroll appropriate subjects in clinical trials or retain patients in the clinical trials we perform, we may not be able to complete these trials on a timely basis, or at all.

Identifying and qualifying a sufficient number of eligible subjects to participate in clinical trials of our product candidates, and retaining the subjects once qualified, is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit appropriate subjects to participate in testing our product candidates as well as completion of required follow-up periods. If subjects are unwilling to participate in our trials or complete the required follow-up periods, the timeline for recruiting subjects, conducting trials and obtaining marketing approval of potential products may be delayed.

Difficulty or delays in patient recruitment into our trials could result in increased costs, delays in advancing our product development, revisions to trial design or endpoints**,** or termination of the clinical trials altogether. Many factors affect subject enrollment and retention, including:

- The size and nature of the subject population;
- The number and location of clinical sites we activate;
- The proximity of subjects to clinical sites;
- Perceived risks and benefits of the product candidate under trial;
- Competition with other companies for clinical sites or subjects;
- The eligibility and exclusion criteria for the trial;
- The design of the clinical trial;
- Doctor, patient and public awareness of the clinical trials;
- Ability to obtain and maintain subject consent;
- Ability to monitor subjects adequately during and after the administration of the product candidate and the ability of subjects to comply with the clinical trial requirements;
- Risk that enrolled subjects will drop out or be withdrawn before completion; and
- Clinicians' and subjects' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials. Although we have agreements governing their committed activities, we have limited control over their performance, resources, or prioritization of our trials. If we are unable to enroll sufficient subjects in our clinical trials, if enrollment is slower than we anticipate, or if our clinical trials require more subjects than we anticipate, our clinical trials may be delayed or might not be completed. If we experience delays in our clinical trials, the commercial prospects of our product candidates will be harmed. In addition, any delays in completing our clinical trials may increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. In addition, many of the factors that could cause a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of any of our product candidates.

We may fail to successfully identify, in-license, acquire, develop or commercialize potential product candidates.

The success of our business has in the past and is expected to continue depend in part upon our ability to identify and validate new therapeutic targets and identify, develop and commercialize therapeutics, which we may develop ourselves, in-license or acquire from others. Research programs designed to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified.

Our research efforts may initially show promise in identifying potential therapeutic targets or candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- Our methodology, including our screening technology, might not successfully identify medically relevant potential product candidates;
- Our competitors may develop alternatives that render our product candidates obsolete;
- We may encounter product manufacturing difficulties that limit yield or produce undesirable characteristics that increase the cost of goods, cause delays or make the product candidates unmarketable;
- Our product candidates may cause adverse effects in subjects, even after successful initial toxicology studies, or not be tolerable, which may make the product candidates unmarketable;
- Other drugs in the same drug class as our product candidates could develop unforeseen adverse effects that could negatively impact development, approval and/or future sales of our product candidates;
- Our product candidates might not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- Our product candidates might not demonstrate a meaningful benefit to subjects; and
- Our reliance on third parties for research, preclinical studies, or clinical trials may limit our access to data, delay development, or restrict our ability to independently analyze or control development decisions.

Additionally, we may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business, operating results and prospects and could potentially cause us to cease operations.

Our current or future product candidates may cause undesirable side effects or have other properties that could delay or prevent their marketing approval, limit their commercial potential, or result in significant negative consequences following any marketing approval.

Undesirable side effects caused by our product candidates in clinical trials could cause us or regulatory authorities to interrupt, delay, or halt one or more clinical trials, including issuing a clinical hold, and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or other regulatory authorities. Clinical trial results may reveal safety signals that are dose-dependent, population-specific, or cumulative over time, Results of our trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

Should our clinical trials of our product candidates reveal undesirable side effects, we could suspend or terminate our trials or the FDA or other regulatory authorities as well as IRBs or ECs could order us to suspend or cease clinical trials. The FDA or other regulatory authorities could also deny approval of our product candidates for any or all targeted indications or only for a limited indication or patient population or could require label warnings and/or precautions, contraindications, including black box warnings, additional wording regarding adverse reactions, post-market studies, testing and surveillance programs or other conditions including distribution restrictions or other risk management mechanisms under a risk evaluation and mitigation strategy ("REMS"). Drug-related side effects could affect subject recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any such outcomes could materially and adversely affect our development timelines, costs, and prospects.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our current or future product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. Additionally, if one or more of our product candidates receives marketing approval, and we or others (regulatory agencies, consumers, etc.) later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- We may suspend marketing of, or withdraw or recall, such product;
- Regulatory authorities may withdraw approvals of such product;
- Regulatory authorities may require additional warnings on the label or other label modifications;
- Regulatory authorities may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- Regulatory authorities may require the establishment or modification of a REMS or other restrictions on marketing and distribution, or may require the establishment or modification of a similar strategy that may, for instance, require us to issue a medication guide outlining the risks of such side effects for distribution to patients or restrict distribution of our products and impose burdensome implementation requirements on us;
- Regulatory authorities may require that we conduct post-marketing studies; and
- We could be sued and held liable for harm caused to subjects or patients.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate or otherwise materially harm the commercial prospects for the product candidate, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

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

As product candidates are developed through preclinical studies to late-stage clinical trials toward regulatory approval and commercialization, it is common that various aspects of the manufacturing process, such as methods and formulation, are altered in an effort to optimize processes and results. Such changes may introduce comparability risk and carry the risk that they will not achieve these intended objectives. Any such changes could cause our product candidates to perform differently, affect the results of planned clinical trials or other future clinical trials conducted with the optimized materials, and limit our ability to rely on data from clinical trials conducted with an earlier version of our product candidate Manufacturing or formulation changes may require additional nonclinical testing, clinical bridging studies, regulatory notifications, or regulatory approvals.

Similarly, changes in the location of manufacturing or addition of manufacturing facilities may increase our costs and require additional studies and FDA approval. This may require us to ensure that the new facility meets all applicable regulatory requirements, is adequately validated and qualified, and conduct additional studies of product candidates manufactured at the new location. Any of the above could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay regulatory approval of our product candidates and jeopardize our ability to commence product sales and generate revenue.

Biological products are highly complex and expensive, and if the third-party manufacturers we contract with are unable to provide quality and timely offerings to our clinical trial sites, our clinical trials might be delayed.

Our product candidate, abdakibart (AVTX-009), is a biologic. The process of manufacturing biologics and their components is complex, expensive, highly-regulated and subject to multiple risks.

Manufacturing biologics is susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. Furthermore, the development of biological products involves a lengthy and expensive process with an uncertain outcome, which might require us to incur additional unforeseen costs to complete our clinical trials. Such issues may require investigation, remediation, or regulatory reporting, further increasing costs and delays.

Although we are working with third parties to develop reproducible and commercially viable manufacturing processes for our biological product candidates, doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency, and timely availability of reagents or raw materials. Any failure by our third-party manufacturers could materially delay our clinical trials, regulatory submissions, or commercialization efforts and materially harm our business.

We face substantial competition and rapid technological change and the possibility that others may discover, develop or commercialize products before or more successfully than us.

Competitive timing risk is heightened by our clinical-stage status and limited commercial infrastructure. The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We face competition with respect to our current product candidates and will face competition with respect to any future product candidates from major pharmaceutical companies, specialty pharmaceutical companies, governmental agencies, research institutions and biotechnology companies worldwide. Many of our competitors have significantly greater financial, technical manufacturing, regulatory, commercial, and human resources and may be better positioned to withstand market volatility or invest across multiple programs simultaneously. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our competitors may obtain marketing approval of their products more rapidly than we may or secure regulatory exclusivity, pricing advantages, or preferred formulary placement or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile and better tolerability than our products and these competitors may also be more successful than us in manufacturing and marketing their products.

Our competitors will also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Competition for clinical trial sites and patient populations may intensify as additional trials are initiated in overlapping indications**.**

Additionally, many of our competitors and their collaborators may have significantly greater experience than we do in the following:

- Identifying and validating targets;
- Screening compounds against targets;
- Manufacturing pharmaceutical and biological products at scale;
- Preclinical and clinical trials of potential pharmaceutical products; and
- Obtaining FDA and other regulatory clearances.

There are now approved therapies to treat the conditions our product candidates seek to address and there could be other approved therapies in the future, consequently, competition in these markets is intense. Many of these approved products are or may become well-established therapies and widely accepted by physicians, patients and third-party payors. Some of these therapies are protected by patents and regulatory exclusivities, while others are available or may become available as generic or biosimilar products, which could further limit market opportunity.

Our products might not achieve adequate market acceptance among physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if our product candidates have or receive marketing approval, they might not gain adequate market acceptance among physicians, patients and others in the medical community. Our commercial success also depends on coverage and adequate reimbursement of our product candidates by third-party payors, including government payors, generally, which may be difficult or time-consuming to obtain, may be limited in scope or might not be obtained in all jurisdictions in which we may seek to market our products. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- The efficacy and safety profile of our product candidates, including relative to marketed products and product candidates in development by third parties;
- Prevalence and severity of any side effects of our product candidates;
- Relative convenience and ease of administration of our product candidates;
- Cost effectiveness of our product candidates;
- The claims we may make for our product candidates based on the approved label or any restrictions placed upon our marketing and distribution of our product candidates;
- The time it takes for our product candidates to complete clinical development and receive marketing approval;
- How quickly and effectively we alone, or with a partner, can market, launch, and distribute any of our product candidates that receive marketing approval relative to competing products;
- The ability to commercialize any of our product candidates that receive marketing approval;
- The adequacy of our or our partners' sales, medical affairs, and market-access capabilities;
- The price of our approved product candidates, including in comparison to branded or generic competitors and relative to alternative treatments;
- Potential or perceived advantages or disadvantages of our approved product candidates over alternative treatments;
- The ability to collaborate with others in the development and commercialization of new products;
- Whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare;
- The ability to establish, maintain and protect intellectual property rights related to our product candidates;
- The entry of generic versions of any of our approved products onto the market;
- The number of products in the same therapeutic class as our product candidates;
- The effect of current and future healthcare laws on our drug candidates;
- The ability to secure favorable managed care formulary positions for our approved product candidates, including federal healthcare program formularies;
- The ability to manufacture commercial quantities of any of our product candidates that receive marketing approval;
- Acceptance of any of our product candidates that receive marketing approval by physicians and other healthcare providers; and
- Potential post-marketing commitments and post-marketing requirements imposed on an approved product candidate by regulatory authorities, such as patient registries.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, third-party payors and patients, we might not generate or derive sufficient revenue from that product
and may not achieve or sustain profitability, which could materially and adversely affect our business, financial condition, results of operations, and prospects.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Our concentration of resources and reliance on abdakibart (AVTX-009) materially increases our exposure to this risk.

Given our limited resources, we have prioritized certain product candidates over others at our management's discretion. These prioritization decisions necessarily involve significant judgment based on incomplete information. We have also de-prioritized development of certain product candidates. We continually evaluate our capital allocation for each product candidate, and, in the future, may de-prioritize or cancel the development of certain product candidates. Our decisions concerning the allocation of research, collaboration, management, and financial resources toward particular proprietary molecules in our library, product candidates or therapeutic areas may not accurately reflect their ultimate commercial potential and may divert resources away from better opportunities.

Similarly, our decisions to delay, terminate or collaborate with third parties in respect of certain product development programs may limit our future strategic flexibility and could cause us to miss valuable opportunities. If the development of our product candidates is unsuccessful or, if successful but the products do not achieve an adequate level of market acceptance, we may lack the financial or operational capacity to pursue alternative programs. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Our spending on current and future research and development programs and product candidates for specific indications might not yield any commercially viable products. 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. Our focus and reliance on abdakibart (AVTX-009) increases the risk of this exposure.

Risks Related to Regulatory Approval of Our Product Candidates

The marketing approval processes of the FDA and other regulatory authorities are lengthy, time-consuming, costly and inherently unpredictable. Our inability to obtain regulatory approval for our product candidates would substantially harm our business and prospects.

The time required to develop and to obtain approval from regulatory authorities to market a new drug or biological product is unique to each product and indication. It typically takes many years in nonclinical and clinical development and depends upon numerous factors including but not limited to the severity of the target disease, the availability of alternative therapies, and evolving regulatory expectations. In addition, regulatory guidance, laws and regulations as well as interactions with regulatory authorities may change the course of development for a product candidate. Further, the type and amount of preclinical and clinical data necessary to gain approval may change during the course of product candidates development and may vary among countries. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities and often clinical sites by, the relevant regulatory authority. Our current or future product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval. Submission of an NDA or BLA to the FDA generally requires an application fee. We may also be required to pay significant fees for regulatory advice, inspections, and post-approval commitments. The filing of an NDA or BLA for any of our product candidates may be delayed due to our lack of financial resources to pay such user fee or otherwise support the regulatory review process.

The FDA may refuse to accept any application for filing, may place a clinical hold on a clinical trial at any stage, or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. The U.S. Supreme Court's decision in July 2024 to overturn established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays or changes and may result in inconsistent regulatory outcomes or extended review timeline. Our product candidates could fail to receive regulatory approval from the FDA or other regulatory authorities for many reasons, including:

- Such regulatory authorities may disagree on the design or conduct of our key phase 2 and pivotal phase 3 clinical trials, including the overall study design, primary and secondary endpoints, number of patients, statistical analysis plan, or our proposed product indication. For instance, the FDA may find that the study designs we are utilizing in a planned clinical trial do not constitute an adequate and well-controlled study supportive of approval. The FDA also might not agree with the proposed quality of life scales and other evaluation tools that we may use in a clinical trial to assess the efficacy of a product candidate;
- Such regulatory authorities may disagree with our development plans, including the number of studies and types of studies planned to support approval for each product and indication;

- Our failure to demonstrate to the satisfaction of the FDA or other regulatory authorities that a product candidate is safe and effective for each proposed indication;
- Our clinical trials may fail to meet statistical significance on their primary endpoints, which is required for a positive study;
- We may fail to demonstrate that a product candidate's benefits outweigh its risks, including due to better than expected performance of placebo arms;
- The FDA or other regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- The FDA or other regulatory authorities may require an advisory committee review and the advisory committee may recommend against approval;
- Our product candidates may fail to qualify for, or maintain, accelerated approval, priority review, breakthrough therapy, fast track or similar regulatory designations;
- Data collected from clinical trials of our product candidates may be insufficient to support the submission of a marketing application or to obtain marketing approval, and the FDA or other regulatory authority may require additional studies to show a product candidate is safe and/or effective;
- We may fail to obtain approval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; or
- There may be changes in precedent, regulatory guidance, laws and regulations that render our preclinical and clinical data insufficient for approval.

The FDA or other regulatory authority may require more information, including additional preclinical or clinical studies to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain approval to market our product candidates, which would significantly harm our business, results of operations and prospects. In addition, even if we were to obtain approval, regulatory authorities may approve any or all of our product candidates for fewer or more limited indications than we request, may require that contraindications, warnings or precautions be included in the product labeling, including a black-box warning, may grant approval with a requirement of post-marketing clinical trials or other post-market requirements, or post-marketing commitments or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate or impose restrictions that materially limit market adoption. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Even if we complete the necessary clinical trials, we cannot predict when or if we will obtain marketing approval to commercialize a product candidate or the approval may be for a narrower indication than we expect or may be conditioned on costly post-approval obligations.

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if our product candidates demonstrate safety and efficacy in clinical trials, regulatory agencies might not complete their review processes in a timely manner, or we might not be able to obtain marketing approval. Additional delays may result if the FDA or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials and the review process. Further, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Regulatory authorities may approve a product candidate for fewer or more limited indications than requested, may impose significant limitations in the form of narrow indications, warnings, including black-box warnings, precautions or contra-indications with respect to conditions of use, additional adverse reactions information or may grant approval subject to the performance of post-marketing clinical trials or other post-marketing requirements, including a REMS. Our drugs, if approved, may be required to carry warnings comparable to this and other class-wide warnings. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Even if our product candidates receive marketing approval, we will still be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and diversion of management attention. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and we may be subject to administrative sanctions or penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Even if we obtain marketing approval for a product candidate, we would be subject to ongoing requirements by the FDA and other regulatory authorities governing the manufacturing, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and annual reporting of safety and other post-market information. The FDA and other regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or other regulatory authorities become aware of new safety information after approval of any of our product candidates, they may withdraw approval, require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, any marketing approvals that we obtain for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval or contain requirements for potentially costly post-marketing testing and other requirements, including phase 4 clinical trials, imposition of a REMS and surveillance to monitor the safety and efficacy of the product candidate for an extended period of time.

In addition, manufacturers of drug products and their facilities, including contracted facilities, are subject to periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with the facility where the product is manufactured, we may be subject to reporting obligations and a regulatory agency may impose restrictions on that product, the manufacturing facility, us, or our suppliers, including requesting recalls or withdrawal of the product from the market or suspension of manufacturing or distribution. If we, our product candidates, our contractors, the manufacturing facilities for our product candidates or others working on our behalf fail to comply with applicable regulatory requirements, either before or after marketing approval, a regulatory agency may:

- Issue Warning Letters, Untitled Letters, or FDA Form 483s, all of which document compliance issues identified by the FDA;
- Mandate modifications to promotional materials or labeling, or require us to provide corrective information to healthcare practitioners;
- Require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- Seek an injunction or impose civil or criminal penalties or monetary fines, restitution or disgorgement, as well as imprisonment;
- Suspend or withdraw marketing approval;
- Suspend or terminate any ongoing clinical studies;
- Refuse to approve pending applications or supplements to applications filed by us;
- Debar us from submitting marketing applications, exclude us from participation in federal healthcare programs, require a corporate integrity agreement or deferred prosecution agreements, debar us from government contracts and refuse future orders under existing contracts;
- Suspend or impose restrictions on operations, including restrictions on marketing, distribution or manufacturing of the product, or the imposition of costly new manufacturing requirements or use of alternative suppliers; or
- Seize or detain products, refuse to permit the import or export of products, or request that we initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to continue our development programs, commercialize our products and generate revenue and may require us to incur substantial remediation costs.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA and other federal agencies, state attorneys general and the public. While the FDA does not restrict physicians from prescribing approved drugs for uses outside of the drugs' approved labeling, known as off-label use, pharmaceutical manufacturers are strictly prohibited from promoting and marketing their products for such uses. Violations, including promotion of products for off-label uses, are subject to enforcement letters, inquiries, investigations, civil and criminal sanctions by the government, corporate integrity agreements, deferred prosecution agreements, debarment from government contracts and refusal of future orders under existing contracts, and exclusion from participation in federal healthcare programs. Additionally, other regulatory authorities will heavily scrutinize advertising and promotion of any product candidate that obtains approval outside of the United States under their respective national laws.

In the United States, engaging in the impermissible promotion of any products for off-label uses can also subject a company to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines, debarment from government contracts and refusal of future orders under existing contracts, deferred prosecution agreements, and corporate integrity agreements with governmental authorities that materially restrict the manner in which a company promotes or distributes drug products. These false claims statutes include the federal civil False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual will share in any fines or settlement funds. If the government does not intervene, the individual may proceed on his or her own. If we do not lawfully promote our approved products, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations and prospects.

The FDA's or other regulatory authorities policies may change, and additional government guidance, laws and regulations may be enacted that could prevent, limit or delay marketing approval, and the sale and promotion of our product candidates or increase the costs associated with regulatory compliance. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Disruptions to the FDA, the SEC and other governmental agencies and regulatory authorities caused by funding shortages, changes in leadership and policy, or global health concerns could hinder the 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 and results of operations.

The ability of the FDA to review regulatory filings and our ability to commence human clinical trials can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and contractors, the FDA's ability to accept and process the payment of user fees and accept the payment of user fees, and statutory, regulatory, leadership and policy changes. Average review times at the agency have fluctuated recently and may continue to fluctuate in the future. In addition, government funding of the SEC, and other governmental agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable and may be affected by changes in congressional or executive priorities.

Disruptions at the FDA and other agencies or comparable foreign regulatory authorities, may also slow the time necessary for the review and approval of applications for clinical trials or marketing authorization, which would adversely affect our business. For example, action by the Trump Administration to limit federal agency budgets and personnel has led to reductions to the FDA's budget, employees, and operations, which in certain circumstances has led to slower response times and longer review periods and inspection backlogs. These factors may affect our ability to progress development of our product candidates or obtain regulatory approval for our product candidates. If 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.

If a prolonged government shutdown occurs, or if global health concerns or other emergencies prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, conduct manufacturing or clinical site inspections, or hold advisory committee meetings could be significantly impacted, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations or delay SEC effectiveness of registration statements or other filings.

There is substantial uncertainty as to how and to what extent the leadership of the FDA and the Trump Administration will continue to seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates and any products for which we obtain approval. Additionally, the administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of new therapeutic candidates or alter regulatory standards in ways that increase development timelines or costs.

We are conducting clinical trials for abdakibart (AVTX-009) at sites in foreign jurisdictions, and the FDA might not accept data from trials conducted in such locations.

In addition to our sites within the United States, we are conducting our phase 2 trial of abdakibart (AVTX-009) for the treatment of HS at sites in foreign jurisdictions. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. Generally, the patient population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to seek approval in the United States and the data must be applicable to the U.S. population and medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations including but not limited to including requirements relating to good clinical practice, trial monitoring, and data integrity. There can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from any of our clinical trials that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of the product candidate. In addition, any clinical trials outside of the United States might be subject to delays and risks surrounding geopolitical events or differences in regulatory enforcement practices.

We may fail to achieve our development and regulatory milestones on expected timelines, or at all, which could materially and adversely affect our business, financial condition, results of operations and prospects.

As a clinical-stage biopharmaceutical company, the value of our business depends substantially on our ability to advance our product candidate(s) through preclinical and clinical development and to obtain regulatory approval in a timely manner. Our development programs are subject to significant risks and uncertainties, and we may fail to meet publicly disclosed or internally anticipated milestones for a variety of reasons, many of which are outside of our control.

We establish development milestones based on a variety of assumptions, including patient enrollment rates, clinical site initiation timelines, manufacturing readiness, data availability, regulatory review periods, and the performance of third-party service providers.

These assumptions may prove to be inaccurate. Clinical trials are inherently unpredictable and may be delayed or terminated due to, among other things: slower-than-expected patient enrollment or higher screen failure rates; delays in clinical site activation or staffing shortages at clinical sites; protocol amendments, safety concerns, or unfavorable interim data; variability in trial results or failure to achieve trial endpoints; manufacturing delays, supply chain disruptions, or product quality issues; delays in the release, analysis or validation of clinical data; feedback from regulatory authorities requiring additional data, modifications to trial design, or additional trials; challenges in scaling manufacturing processes or transferring manufacturing to third parties; and reliance on CROs, contract manufacturing organizations ("CMOs"), and other third parties over whom we have limited control. If we are unable to meet anticipated milestones for our clinical development programs, including timing of trial initiation, enrollment, data readouts, regulatory submissions, or regulatory approvals, our business may be materially harmed. Delays in achieving milestones may result in increased development costs, require us to raise additional capital sooner than expected, and divert management's attention and resources. In addition, failure to meet publicly disclosed milestones or guidance could result in significant volatility in our stock price, loss of investor confidence, increased litigation risk, and diminished ability to access capital on favorable terms, or at all. We may revise, suspend, or terminate one or more of our development programs if interim or final data are negative or inconclusive, if regulatory authorities impose additional requirements, or if we determine that the program is no longer commercially viable. Even if we ultimately complete a clinical trial, delays in data analysis, regulatory review, or manufacturing scale-up may prevent us from achieving regulatory approval or commercialization within expected timeframes. Because our operating expenses are primarily driven by development activities, delays in our clinical programs may materially impact our cash runway and require us to seek additional financing, which may not be available on acceptable terms or at all. Any of these events could materially and adversely affect our business, financial condition, results of operations and prospects.

Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidates outside the United States, which would limit our market opportunities and adversely affect our business.

In order to market and sell our products in other jurisdictions, we must be granted approval and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional product candidate testing and additional administrative review periods. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval as well as other risks. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country might not be accepted by regulatory authorities in other countries. If we fail to comply with the regulatory requirements in international markets and receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We might not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions. Approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. Also, regulatory approval for any of our product candidates may be withdrawn or conditioned on post-approval obligations. The failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval in another jurisdiction. Our failure to obtain approval of any of our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business prospects could decline.

Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties that could materially adversely affect our business and profitability.

We are not permitted to market or promote any of our current or future product candidates before we receive regulatory approval from the applicable regulatory authority in that market, and we may never receive such regulatory approval for any of our current or future product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our current or future product candidates, and we cannot predict success in these jurisdictions. If we obtain approval of our current or future product candidates and ultimately commercialize our current or future product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- Differing regulatory requirements in foreign countries, such that obtaining regulatory approvals outside of the U.S. may take longer and be more costly than obtaining approval in the U.S.;
- Challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;
- Our customers' ability to obtain reimbursement for our current or future product candidates in foreign markets;
- The burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- Foreign reimbursement, pricing and insurance regimes;
- Unexpected changes in tariffs, trade barriers and regulatory requirements;
- Different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- Import or export licensing requirements;

- Longer accounts receivable collection times;
- Longer lead times for shipping;
- Language barriers for technical training;
- Reduced protection of intellectual property rights in some foreign countries;
- The existence of additional potentially relevant third-party intellectual property rights;
- Economic weakness, including inflation, or political instability in particular foreign economies and markets;
- Compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- Foreign taxes, including withholding of payroll taxes;
- Foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- Difficulties staffing and managing foreign operations;
- Workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- Potential liability under the Foreign Corrupt Practices Act of 1977 (the "FCPA") or comparable foreign regulations;
- The interpretation of contractual provisions governed by foreign laws in the event of a contract dispute;
- Production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- Business interruptions resulting from geo-political actions, including war and terrorism.

Foreign sales of our current or future product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs (including tariffs that have been or may in the future be imposed by the United States or other countries or by sanctions regimes that limit cross-border transactions.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, including the FCPA, anti-money laundering, export control, sanctions, and other trade laws and regulations, which we collectively refer to as "Trade Laws," prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector (including government officials and employees of government-owned or government-controlled entities). Anti-corruption and anti-bribery laws have been enforced aggressively in recent years and are interpreted broadly. In addition, U.S. export control and sanctions laws (including those administered by the U.S. Department of the Treasury's Office of Foreign Assets Control and the U.S. Department of Commerce) can restrict, prohibit or impose licensing requirements on certain transactions and dealings with designated countries, entities and individuals. Violations of trade laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. As we increase our activities outside the U.S., which may include increased interactions with officials and employees of government agencies or state-owned or -affiliated entities, our risks under these laws may increase. Noncompliance with these laws could subject us to investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, adverse media coverage, and other consequences. We may be held liable for the actions of our third-party intermediaries, including CROs, investigators, consultants, contractors and partners, even if we did not authorize or have actual knowledge of the improper conduct. Any investigations, actions or sanctions could harm our business, results of operations, and financial condition. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations in connection with our clinical development activities.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In addition, many countries outside the U.S. have limited government support programs that provide for reimbursement of products such as our product candidates, with an emphasis on private payors for access to commercial products. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

Current and future healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

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

The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by legislative initiatives. Current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any FDA approved product. If reimbursement of our products is unavailable or limited in scope, our business could be materially harmed. For more information, please see "*Business—Government Regulation and Product Approval—Healthcare Reform and Other Regulatory Changes*."

Third party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In the U.S. and certain other jurisdictions, there have been, and are expected to continue to be, a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our products profitably. In addition, significant uncertainty exists in the U.S. and certain other jurisdictions regarding the provision and financing of healthcare because the elected administrations in such countries have publicly declared their intention to review and potentially significantly modify the current legal and regulatory framework for the healthcare system including through drug pricing and reimbursement reforms.

We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect:

- The demand for any of our product candidates, if approved;
- The ability to set a price that we believe is fair for any of our product candidates, if approved;
- Our ability to generate revenues and achieve or maintain profitability;
- The level of taxes that we are required to pay; and
- The availability of capital.

For example, recent CMS proposals from November 2025 and December 2025, including the GLOBE, GUARD, and GENEROUS, could materially impact the Company's revenue. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability and could materially reduce net realized prices.

The FDA announced in July 2025 a fast-track priority review voucher for drugs whose manufacturers commit to setting a price in line with drug pricing offered in economically similarly situated countries around the world. For example, the FDA has announced a "national priority" voucher pilot program intended to accelerate development and review of certain drugs and biologics aligned with U.S. national health priorities. The effects of these proposals and how these proposals will be implemented are not yet known and could depend on future guidance and agency discretion.

Further, the Inflation Reduction Act of 2022 (the "IRA") was recently revised to broaden the exemption from the drug price negotiation program for drugs with orphan designations. Previously under the IRA, orphan drugs were exempted from the Medicare drug price negotiation program; but this exemption was restricted to drugs with only one orphan designation and for which the only approved indication is for that rare disease or condition. If a product were to receive multiple orphan designations or had multiple approved indications, it would not have qualified for the orphan drug exemption. Under the One Big Beautiful Bill Act of 2025, this restriction was eliminated; and effective for the 2028 initial price applicability year, all orphan drugs, regardless of the number of orphan designations or indications, are exempt from the Medicare drug price negotiation program, provided that all approved indications are for rare diseases.

Any of the foregoing measures (and related implementing guidance, rulemaking, enforcement activity or private litigation) could materially reduce pricing flexibility, increase rebates or discounts, narrow coverage, delay patient access, and adversely affect our ability to commercialize abdakibart (AVTX-009) or any future product candidates, if approved.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. 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. We also could incur significant costs associated with civil or criminal fines and penalties.

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 maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

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

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the U.S. and abroad; or laws that require the reporting of financial information or data accurately or compliance with securities laws, including laws relating to insider trading and selective disclosure. In particular, sales, marketing, patient support and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Other activities subject to these laws include the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, 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 comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. 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 civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that 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 criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment, reputational harm, exclusion from participation in government 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 and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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. 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.

Ongoing changes to healthcare laws and regulations may increase the difficulty of and costs associated with commercializing our products and may affect the prices we are paid for those products and the demand for such products.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates or therapies profitably. The success of our product candidates, if approved, depends on the availability of adequate coverage and reimbursement from third party payors, including government agencies, private health insurers and health maintenance organizations.

There is significant uncertainty related to the insurance coverage and reimbursement of any newly approved product, novel biologic therapies and drugs approved based on limited or surrogate endpoints or requiring specialized administration. All the therapeutic indications approved by the relevant authorities may not be covered or reimbursed. In addition, we cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates because they are new therapies in evolving reimbursement environments, and payors may adopt new or more restrictive coverage policies following approval. For more information "Business—Government Regulation and Product Approval—Coverage and Reimbursement."

In the U.S. and some other jurisdictions, patients generally rely on third party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the U.S., and commercial payors are critical to new product uptake and commercial success.

Government authorities and other third party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. In the U.S., the principal decisions about reimbursement for new medicines are typically made by the CMS, an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare, and private payors often follow CMS's coverage decisions. Other jurisdictions have agencies, such as the National Institute for Health and Care Excellence in the U.K., that evaluate the use and cost-effectiveness of therapies, which impact the utilization and price of the medicine in such jurisdiction and may impose additional evidence development requirements.

In the U.S., no uniform policy of coverage and reimbursement for products exists among third party payors. As a result, obtaining coverage and reimbursement approval of a product from a third party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each potential payor, with no assurance that coverage and adequate reimbursement will be obtained from all or any of them. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might be insufficient or may require co-insurance or co-payments that patients find unacceptably high, which may prevent us from achieving or sustaining profitability. Additionally, third party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our genome editing products.

In addition, each country in which we seek approval to market our product candidates has unique laws and market practices regulating coverage and reimbursement for human therapeutics. Market acceptance and sales of our products in each country will depend on our ability to meet each of these jurisdiction's requirements for coverage and reimbursement. Further, changes to the country's existing requirements may also affect our ability to commercialize our products in the future, or achieve profitability from their sale. In many jurisdictions, payors may require head-to-head comparative effectiveness data, real-world evidence, or additional post-approval studies as a condition of coverage or favorable reimbursement.

We may be subject to certain regulations, including federal and state healthcare fraud and abuse laws, physician payment transparency laws, anti-bribery and anti-corruption laws and health information privacy and security laws. Any actual or perceived failure to comply with these regulations could have a material adverse effect on our business and financial condition.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be subject to various federal and state healthcare laws, including, without limitation, fraud and abuse laws, false claims laws, data privacy and security laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers and patients. These laws may impact, among other things, our proposed sales, marketing and education programs. Additionally, we may be subject to state and foreign equivalents of such healthcare laws and regulations, some of which may be broader in scope and may apply regardless of the payor, as well as patient privacy regulation by both the federal government and the states in which we conduct our business. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge and may not comply under one or more of such laws, regulations, and guidance. Law enforcement authorities are increasingly focused on enforcing fraud and abuse laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our current and future business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. If our operations, including our arrangements with physicians and other healthcare providers are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs (such as Medicare and Medicaid), and imprisonment, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our financial results. For more information, please see "*Business—Government Regulation and Product Approval—Other Healthcare Laws and Compliance Requirements*."

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations.

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

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

Risks Related to the Commercialization of Our Product Candidates

We might not be successful in our efforts to develop and commercialize our product candidates.

Our continued development of our product candidates will be dependent on receiving positive data that, in our judgment, merits advancing such programs. Even if we are successful in continuing to build and expand our pipeline, the product candidates that we identify might not be suitable for clinical development and commercialization, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance. Similarly, even if the FDA accepts our INDs, there is no guarantee that we will be successful in our efforts to advance our product candidates through development, or if approved, to commercialization.

If, in the future, we are unable to establish sales, marketing and distribution capabilities or enter into licensing or collaboration agreements for these purposes, we might not be successful in commercializing our product candidates.

We do not currently have a sales or marketing infrastructure. To develop our internal sales, distribution and marketing capabilities for product candidates, we will have to invest significant financial and management resources, some of which will be committed prior to any confirmation that any product candidates will be approved.

There are risks involved with both establishing our own sales and marketing and patient support capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any drug 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.

For product candidates for which we decide to perform sales, marketing and distribution functions ourselves, we could face a number of additional risks, including:

- Our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- Inability of marketing personnel to develop effective marketing materials;
- The inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the clinical benefits of our products to achieve market acceptance;
- 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;
- The costs associated with training sales personnel on legal compliance matters and monitoring their actions;
- Liability for sales personnel failing to comply with applicable legal requirements; and
- Unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Where and when appropriate, we may elect to utilize contract sales forces or strategic partners to assist in the commercialization of our product candidates. If we enter into arrangements with third parties to perform sales, marketing and distribution services for our products, the resulting revenues or the profitability from these revenues to us are likely to be lower than if we had sold, marketed and distributed our products ourselves. In addition, we might 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 these third parties may fail to devote the necessary resources and attention to sell, market and distribute our products effectively. Such third parties may also not comply with the applicable regulatory requirements, which could potentially expose us to regulatory and legal enforcement actions and reputational harm.

Even if we receive marketing approval for abdakibart (AVTX-009) or future product candidates, our current or future product candidates may not achieve broad market acceptance, which would limit the revenue that we generate from their sales and could prevent us from achieving or sustaining profitability.

The commercial success of our current or future product candidates, if approved by the FDA or other applicable regulatory authorities, will depend upon the awareness and acceptance of our current or future product candidates among the medical community, including physicians, patients and healthcare payors. Market acceptance of our current or future product candidates, if approved, will depend on a number of factors, including, among others:

- The efficacy of our current or future product candidates as demonstrated in clinical trials, and, if required by any applicable regulatory authority in connection with the approval for the applicable indications, to provide patients with incremental health benefits, as compared with other available medicines;
- Limitations or warnings contained in the labeling approved for our current or future product candidates by the FDA or other applicable regulatory authorities; Including but not limited to any boxed warning, contraindications, limitations of use, or requirements for a REMS;
- The clinical indications for which our current or future product candidates are approved including the breadth of the indicated patient population;
- Availability of alternative treatments already approved or expected to be commercially launched in the near future;
- The potential and perceived advantages of our current or future product candidates over current treatment options or alternative treatments, including future alternative treatments;
- The willingness of the target patient population to try new therapies or treatment methods and of physicians to prescribe these therapies or methods;
- The need to dose such product candidates in combination with other therapeutic agents, and related costs;
- The strength of marketing and distribution support and timing of market introduction of competitive products;
- Publicity concerning our products or competing products and treatments;
- Pricing and cost effectiveness;
- The effectiveness of our sales and marketing strategies;
- Our ability to increase awareness of our current or future product candidates;
- Our ability to obtain sufficient third-party coverage or reimbursement; including the adequacy of reimbursement for administration, monitoring and other ancillary services; or
- The willingness of patients to pay out-of-pocket in the absence of third-party coverage.

If our current or future product candidates are approved but do not achieve an adequate level of acceptance by patients, physicians and payors, we may not generate sufficient revenue from our current or future product candidates to become or remain profitable. Before granting reimbursement approval, healthcare payors may require us to demonstrate that our current or future product candidates, in addition to treating these target indications, also provide incremental health benefits to patients including comparative effectiveness versus existing therapies and real-world evidence of value. Our efforts to educate the medical community, patient organizations and third-party payors about the benefits of our current or future product candidates may require significant resources and may never be successful.

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

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and related to the commercial sale of any approved products. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our product candidates or any approved product. For example, we may be sued if any product candidate we test or, if approved, sell allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- Decreased demand for any product candidates or approved products;
- Termination of clinical trial sites or entire trial programs;
- Injury to our reputation and significant negative media attention;
- Withdrawal of clinical trial participants;
- Significant costs to defend the related litigation;

- Substantial monetary awards to trial subjects or patients;
- Loss of revenue;
- Product recalls, withdrawals or labeling, marketing or promotional restrictions;
- Diversion of management and scientific resources from our business operations;
- The inability to commercialize any product candidates that we may develop; and
- A decline in our stock price.

We currently hold product and clinical trial liability insurance coverage, but it might not adequately cover all liabilities that we incur. We might not be able to maintain clinical trial insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If we obtain marketing approval for any of our product candidates and commercialize any products, we may seek to obtain additional insurance coverage for such products; however, such coverage may be unavailable on acceptable terms, or at all, or may not provide adequate coverage against potential liabilities. We might not be able to maintain insurance coverage for our product candidates and our approved products at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A product liability claim or series of claims brought against us, whether or not successful, but particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our reputation and business.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct and monitor our clinical trials. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could hinder our ability to commercialize or obtain marketing approval for our product candidates in a timely manner or at all.

We rely upon and expect to continue to rely upon third-party CROs, CDMOs and other partners for execution of our clinical trials and, while we have agreements governing their activities, we have limited influence over their actual performance and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our preclinical studies or clinical trials, we could be subject to untitled and warning letters or enforcement action that may include civil penalties up to and including criminal prosecution and could delay or prevent regulatory approval of our product candidates.

We, our clinical trial sites, and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA that govern clinical trials. Similar requirements are imposed by comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we, any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other regulatory authorities may require us to perform additional clinical trials before approving our marketing applications, if at all. In addition, if regulatory authorities determine that we or our third parties have not complied with applicable requirements, they may impose a clinical hold, refuse to consider data from a study, or delay or deny approval. In addition, we are required to report certain financial interests of our third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by principal investigators who previously served or currently serve as scientific advisors or consultants to us from time to time and receive cash compensation in connection with such services or otherwise receive compensation from us that could be deemed to impact study outcome, proprietary interests in a product candidate, certain company equity interests, or significant payments of other sorts. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, we must conduct our clinical trials with current or future product produced under applicable cGMP requirements for drug manufacturing. Failure to comply with these regulations may require us to repeat preclinical and clinical trials, which would delay the marketing approval process. Our failure or the failure of third parties that we may contract with to comply with these regulations may require us to repeat some aspects of a specific, or an entire, clinical trial, which would delay the marketing approval process and could also subject us to enforcement action. We also are required to register certain ongoing clinical trials and provide certain information, including information relating to the trial's protocol, on a government-sponsored database, ClinicalTrials.gov, within specific timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Our CROs and clinical trial site personnel are not our employees, and, except for remedies available to us under our agreements with such CROs and clinical trial sites, we cannot control whether they devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. These CROs and clinical trial sites may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position.

If CROs or clinical trial sites do not successfully carry out their contractual duties or obligations or meet expected deadlines, 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 might not be able to obtain marketing approval for or successfully commercialize our product candidates or we may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be adversely affected.

Our reliance on third parties to conduct clinical trials will also result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- Have staffing difficulties;
- Fail to comply with contractual obligations;
- Experience regulatory compliance issues; and
- Form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If our CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us, fail to comply with regulatory requirements, or if they need to be replaced, any clinical trials such CROs are associated with may be extended, delayed or terminated, the development, marketing approval and commercialization of our current or future product candidates may be delayed, we may not be able to obtain marketing approval and commercialize our current or future product candidates, or our development programs may be materially and irreversibly harmed. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures. If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. If our CROs 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, any clinical trials such CROs are associated with may be extended, delayed or terminated, and we may not be able to obtain marketing approval for or successfully commercialize our current or future product candidates.

Switching or adding CROs involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, prospects, financial condition and results of operations.

We use third parties to manufacture all of our product candidates. This may increase the risk that we will not have sufficient clinical or commercial quantities of our product candidates or such quantities at an acceptable cost, which could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates and could harm our business, financial condition and results of operations.

We do not own or operate, and have no plans to establish, any manufacturing facilities for our product candidates. We have limited personnel with experience in drug manufacturing and we lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. As a result, we depend on third parties for the development, testing, scale-up, manufacture, fill-finish, quality control, labeling, packaging, storage and distribution of our product candidates.

We currently outsource all manufacturing of our product candidates to third parties typically without any guarantee that there will be sufficient supplies to fulfill our requirements or that we may obtain such supplies on acceptable terms. Any delays in obtaining adequate supplies with respect to our product candidates may delay the development or commercialization of our other product candidates or require us to incur additional costs to secure alternative suppliers.

In addition, we do not currently have agreements with all third-party manufacturers for the long-term commercial supply of our product candidates. We may be unable to enter agreements for commercial supply with third-party manufacturers, or may be unable to do so on acceptable terms. Even if we enter into these agreements, the various manufacturers of each product candidate will likely be single source suppliers to us for a significant period of time.

The facilities used by our contract manufacturers to manufacture our product candidates may be inspected by the FDA after we submit a BLA and prior to approval thereof. While we are ultimately responsible for the manufacture of our product candidates, other than through our contractual arrangements, we do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMP requirements for manufacture of both active drug substances and finished drug products for clinical supply and eventually for commercial supply, if we receive regulatory approval. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. Failure of our contract manufacturers to comply with the applicable regulatory requirements may also subject us to regulatory enforcement actions. In addition, other than through our contractual agreements, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel.
If the FDA or other regulatory authorities do not approve these facilities for the manufacture of our product candidates or if approval is withdrawn in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved.

Reliance on third-party manufacturers subjects us to risks that would not affect us if we manufactured the product candidates ourselves, including:

- Reliance on the third parties for regulatory compliance and quality assurance;
- The possible breach of the manufacturing agreements by the third parties because of factors beyond our control;
- The possible misappropriation of our proprietary information, including trade secrets and know-how;
- The possibility of termination or nonrenewal of the agreements by the third parties because of our breach of the manufacturing agreement or based on our own business priorities;
- The disruption and costs associated with changing suppliers, including additional regulatory filings;
- Failure to satisfy our contractual duties or obligations;
- Inability to meet our product specifications and quality requirements consistently;
- Delay or inability to procure or expand sufficient manufacturing capacity;
- Manufacturing and/or product quality issues related to manufacturing development and scale-up or technology transfer;
- Costs and validation of new equipment and facilities required for scale-up;
- Failure to comply with applicable laws, regulations, guidance and standards, including cGMP and similar foreign standards;
- Deficient or improper record-keeping or data integrity issues;
- Contractual restrictions on our ability to engage additional or alternative manufacturers;
- Inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- Termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- Reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we would be unable to manufacture and sell our product candidates or any future product candidate in a timely fashion, in sufficient quantities or under acceptable terms;
- Lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- Lack of access or licenses to proprietary manufacturing methods used by third-party manufacturers to make our product candidates;
- Operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or regulatory sanctions related to the manufacturer;
- Carrier and import disruptions or increased costs that are beyond our control;
- Failure to deliver our products under specified storage conditions and in a timely manner including but not limited to any required cold-chain or other specialized handling conditions;
- Potential changes by third parties to materials, processes, testing, facilities or equipment, which could require us to demonstrate comparability, could lead to delays, or could adversely affect product quality or regulatory compliance; and
- Limited availability or long lead times for critical raw materials, components, or specialized testing, including due to supplier constraints or allocation decisions favoring larger customers.

Our product candidates may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing for us and willing to do so. In addition, the manufacture of biologics requires significant expertise, including the development of advanced manufacturing techniques and process controls. The process is highly complex and we may encounter difficulties in production. These issues may include difficulties with production costs, production yields and quality control, including stability of the product candidate. Further, our product candidates may require new or specialized manufacturing with limited third-party manufacturers available to provide these services. The occurrence of any of these problems could significantly delay our clinical trials or the commercial availability of our product candidates. If our existing third-party manufacturers, or the third parties that we engage in the future to manufacture a product for commercial sale or for our clinical trials, should cease to continue to do so for any reason, we likely would experience delays in obtaining sufficient quantities of our product candidates for us to advance our clinical trials or to meet commercial demand while we identify and qualify replacement suppliers including delays associated with technology transfer, qualification, validation and regulatory submissions.

If for any reason we are unable to obtain adequate supplies of our product candidates or the drug substances used to manufacture them, it will be more difficult for us to develop and commercialize our product candidates and compete effectively and our business, financial condition and results of operations could be materially adversely affected.

Our suppliers are subject to regulatory requirements covering manufacturing, testing, quality control, and record keeping relating to our product candidates, and subject to ongoing inspections by the regulatory agencies. Failure by any of our suppliers to comply with applicable regulations may result in long delays and interruptions to our manufacturing capacity while we seek to secure another supplier that meets all regulatory requirements, as well as market disruption related to any necessary recalls or other corrective actions, including potential clinical holds, delays in regulatory review, or refusal to approve marketing applications.

National and global health or geopolitical situations could have a material adverse impact on our suppliers, which could impede the development or commercialization of our product candidates. including through disruptions in transportation, import/export restrictions, sanctions, labor shortages, inflationary cost pressures, or allocation of manufacturing capacity.

Our manufacturing process needs to comply with FDA regulations relating to the quality and reliability of such processes. Any failure to comply with relevant regulations could result in delays in or termination of our preclinical and clinical programs and suspension or withdrawal of any regulatory approvals or could limit our ability to supply product for clinical trials or, if approved, for commercial sale.

To commercially produce our products either at our own facility or at a third party's facility, we will need to comply with the FDA's cGMP regulations and guidelines. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our current or future product candidates, including leading to significant delays in the availability of our product candidates for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our current or future product candidates. Significant non-compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our current or future product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business and could result in significant additional costs and the diversion of management time and attention.

If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical materials, by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the U.S. governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

We might not succeed in establishing and maintaining development collaborations, which could adversely affect our ability to develop and commercialize product candidates.

A part of our strategy is to enter product development collaborations in the future, including collaborations with major biotechnology or pharmaceutical companies for the development or commercialization of our current and future product candidates. We also face significant competition in seeking appropriate development partners and the negotiation process is time-consuming and complex. We might not succeed in our efforts to establish development collaborations or other alternative arrangements for any of our existing or future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early a stage of development for collaborative effort and/or third parties might not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy or a commercially attractive risk-return profile.

Furthermore, any collaborations that we enter into might not be successful. The success of our development collaborations will depend heavily on the efforts and activities of our collaborators over which we have limited control. Our relationship with any future collaborations may pose several risks, including the following:

- Collaborators have significant discretion in determining the amount and timing of the efforts and resources that they will apply to these collaborations and may prioritize their own internal programs or other third-party collaborations over ours;
- Collaborators might not perform their obligations as expected;
- The nonclinical studies and clinical trials conducted as part of these collaborations might not be successful or may generate results that do not support continued development or commercialization;
- Collaborators might 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 nonclinical study or 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 including changes in management or corporate strategy;
- Collaborators may delay nonclinical studies and clinical trials, provide insufficient funding for nonclinical studies and clinical trials, stop a nonclinical study or clinical trial or abandon a product candidate, repeat or conduct new nonclinical studies or clinical trials or require a new formulation of a product candidate for nonclinical studies or clinical trials which could increase our development costs or delay regulatory timelines;
- 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;
- Product candidates developed in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates or to exercise contractual rights in a manner adverse to us;
- A collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval might not commit sufficient resources to the marketing and distribution of any such product candidate or may fail to achieve anticipated commercial performance;
- Disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any product candidates, may cause delays or termination of the research, development or commercialization of such product candidates, may lead to additional responsibilities for us with respect to such product candidates or may result in litigation or arbitration, any of which would be time consuming and expensive;
- Collaborators might not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation or loss of exclusivity;
- Disputes may arise with respect to the ownership or inventorship of intellectual property developed pursuant to our collaborations;
- Collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability or require us to seek alternative development pathways;
- The terms of our collaboration agreement may restrict us from entering into certain relationships with other third parties, thereby limiting our opportunities or strategic opportunities; 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 or to assume development, manufacturing, or commercialization responsibilities previously borne by the collaborator.

Even if we are successful in our efforts to establish development collaborations, the terms that we agree upon might not be favorable to us and we might not be able to maintain such development collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product candidate are disappointing or fail to meet the collaborator's internal expectations. Any delay in entering into development collaboration agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market. Additionally, collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party sometimes for reasons outside our control. Any such termination or expiration would adversely affect us financially and could harm our business reputation and stock price.

If we fail to establish and maintain additional development collaborations related to our product candidates:

- The development of certain of our product candidates may be terminated or delayed;
- Our cash expenditures related to development of certain of our product candidates would increase significantly and we may need to seek additional financing, which might not be available on favorable terms, or at all;
- We may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for which we have not budgeted;
- We would bear all of the risk related to the development of any such product candidates including but not limited to including regulatory, manufacturing, and commercialization risks;
- We may have to expend unexpected efforts and funds if we are unable to obtain the results of third-party clinical trials or access collaboration-generated data; and
- The competitiveness of any product candidate that is commercialized could be reduced or eliminated entirely.

Risks Related to Intellectual Property

If we are unable to obtain or maintain intellectual property rights, or if the scope of our issued patents are not sufficiently broad, competitors could develop and commercialize products similar or identical to ours, and we might not be able to compete effectively in our market. Furthermore, our US composition-of-matter patent for abdakibart (AVTX-009) expired in February 2026.

Our success depends in significant part on our and our licensors', licensees' or collaborators' ability to file and prosecute patent applications, maintain patents, diligently protect our patent rights and other intellectual property rights and operate without infringing the intellectual property rights of any third party (including patents and other proprietary rights relating to biologics, antibody sequences, manufacturing processes, formulations, methods of treatment, dosing regimens, and delivery). We have filed numerous patent applications both in the United States and in foreign jurisdictions to obtain patent rights to our inventions. We have also licensed third parties' patent portfolios relevant to our technology and may in the future in-license additional intellectual property or enter into other strategic arrangements.

The patent prosecution process is expensive, time-consuming, and uncertain, and we and our current or future licensors, licensees or collaborators might not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors, licensees or collaborators will 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 on them or before any third party files patent applications covering such inventions. Moreover, in some circumstances, we might not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors, licensees or collaborators to secure and maintain adequate patent protection to cover our technology to further our efforts to commercialize our product candidate. Therefore, these licensed patents and patent applications in a manner consistent with the best interests of our business including because of budget constraints, competing priorities, or differing enforcement strategies. If our current or future licensors, licensees or collaborators fail to file, prosecute, or maintain such patents and other intellectual property, such intellectual property rights may be reduced or eliminated. If our licensors, licensees or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised and we may not have adequate contractual remedies or practical ability to cure these issues.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much costly litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaborators' patent rights are highly uncertain. Our and our licensors', licensees' or collaborators' pending and future patent applications might not result in patents being issued which protect our technology or products, in whole or in part, or which effectively allow third parties to commercialize competitive technologies and products. During the course of prosecution, patent examiners may require us or our licensors, licensees or collaborators to narrow the scope of the claims of our or our licensors', licensees' or collaborators' pending and future patent applications to secure allowance, which may limit the scope of patent protection that may be obtained. Our and our licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims adequately cover our products and only in territories in which patents are issued. Even if patents issue, they may be challenged, invalidated, found unenforceable, or construed narrowly, including in post-grant proceedings (such as inter partes review) or other administrative and judicial proceedings.

Furthermore, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio might not provide us with sufficient rights to exclude others from commercializing products similar or identical to our products. Our ability to protect abdakibart (AVTX-009) and any future product candidates may therefore depend on a combination of patents (including potential method-of-use, dosing regimen, formulation, or manufacturing patents), regulatory exclusivities, trade secrets, and other barriers to entry, none of which can be assured. We expect to seek extensions of patent terms, where available in any countries where we are prosecuting patents. Such patent term extensions include the United States Drug Price Competition and Patent Term Restoration Act of 1984, which permits a patent term extension of up to five years beyond the expiration of the patent to compensate the biologics applicant for certain delays caused by the FDA during the drug approval process. However, the applicable authorities, including the FDA in the United States, and any equivalent regulatory authority in other countries, might not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. Moreover, because the calculation of patent term extension awarded to a biologic applicant are based upon FDA delays, whether we receive a patent term extension and, if so, how many years of PTE we are eligible for, is a factor that is outside of our control. In addition, patent term extension may be unavailable if the relevant patent claims, regulatory pathway, or timing requirements are not satisfied.

Our composition of matter patent for abdakibart (AVTX-009) expired in February 2026. If we are unable to obtain extensions to our patents or other means of regulatory exclusivity for our products, the expiration of patents might create opportunities for competitors to enter the market with similar products for our target indications, which could have a material negative impact on our financial results. Without patent protection, we are susceptible to competitors bringing similar products to market, obtaining FDA approval, and achieving regulatory exclusivity prior to us. In addition, once our composition-of-matter patent expires, competitors may be able to develop competing antibodies or biologics that target the same pathway, may seek to rely on their own data packages for approval, and may be able to compete with us on price or access, even if we obtain approval.

Abdakibart (AVTX-009) is classified as a biologic product, which positions the Company to receive biologics reference product exclusivity, also called regulatory exclusivity, in both the United States (twelve years) and Europe (ten years) if and upon receiving marketing approval for the products. We plan to rely on such exclusivity to protect abdakibart (AVTX-009), which has its associated risks. See the risk factor below titled *"As appropriate, we intend to seek all available periods of regulatory exclusivity for our product candidates. However, there is no guarantee that we will be granted these periods of regulatory exclusivity or that we will be able to maintain these periods of exclusivity"* for more information regarding the risks of relying on regulatory exclusivity. However, regulatory exclusivity differs from patent protection and may not prevent competitors from developing and obtaining approval for competing products based on their own full data packages, and may be subject to legal, policy, or legislative change.

As appropriate, we intend to seek all available periods of regulatory exclusivity for our product candidates. However, there is no guarantee that we will be granted these periods of regulatory exclusivity or that we will be able to maintain these periods of exclusivity.

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") created an abbreviated pathway for the approval of biosimilar and interchangeable biological products. This regulatory pathway establishes legal authority for the FDA to review and approve biological products that are biosimilar to or interchangeable with an FDA-licensed reference biologic.

Under the BPCIA, a reference biological product is granted twelve years of exclusivity in the United States from the time of first marketing approval of the product (ten years of data and marketing exclusivity in Europe), and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. In addition, the licensure of a biosimilar product may not be made effective by the FDA until twelve years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still develop and receive approval for a competing version of the reference product if the FDA approves a full biologics license application for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. In addition, the BPCIA includes procedural mechanisms for patent disputes (sometimes referred to as the "patent dance"), and there is substantial uncertainty regarding how these mechanisms may be applied to our products and patents, including the timing and scope of any related litigation.

We believe that our current and any future product candidates we develop as biologic products should qualify for the 12-year period of regulatory exclusivity in the United States (ten years in Europe). While we intend to apply for all periods of exclusivity that we may be eligible for, there is no guarantee that we will receive all such periods of exclusivity. Additionally, under certain circumstances, the FDA may revoke the period of exclusivity. As a result, there is no guarantee that we will be able to maintain a period of regulatory exclusivity for the product, even if such exclusivity is granted. Further, there is a risk that any exclusivity we receive is shortened due to Congressional action or other governmental action, or that the FDA will not consider subject product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Even if exclusivity is granted, competitors may seek to challenge its scope, timing, or applicability, including through administrative or judicial proceedings.

If we breach the license and development agreements related to our product candidates, we could lose the ability to develop and commercialize our product candidates.

Our commercial success depends upon our ability, and the ability of our licensors and collaborators, to develop, manufacture, market and sell our product candidates and use our and our licensors' or collaborators' proprietary technologies without infringing the proprietary rights of third parties. If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose the ability to continue the development and commercialization of our product candidates or face other penalties under these agreements. In particular, we are party to the following agreements for abdakibart (AVTX-009):

- The Lilly License Agreement; and
- The Leap Agreement.

If we fail to comply with the obligations under either of these agreements, including payment terms, our licensors may have the right to terminate either of these agreements, in which event we might not be able to develop, market or sell the relevant product candidate. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in us having to negotiate new or reinstated agreements, which might not be available to us on equally favorable terms, or at all, or cause us to lose our rights under these agreements, including our rights to intellectual property or technology important to our development programs. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, disputes regarding the scope of rights granted, diligence obligations, sublicensing rights, prosecution and enforcement control, or royalty and milestone interpretations could result in delays, increased costs, or loss of rights.

We may be required to make significant payments in connection with our license and development agreements.

We may be required to make significant payments in connection with both of the above listed license and development agreements, including (but not limited to):

- Under the Lilly License Agreement, we will incur development costs for abdakibart (AVTX-009) and are required to make significant payments in connection with the achievement of specified development and regulatory milestones. Additionally, upon commercialization, we are obligated to pay Lilly sales-based milestones and royalties;
- For abdakibart (AVTX-009), we are subject to additional sales-based milestones payable to Leap Therapeutics, Inc.; and
- For abdakibart (AVTX-009), we are subject to additional contingent development milestones in the Leap agreement that are payable to the former AlmataBio stockholders.

If the obligations become due under the terms any of these agreements, we might not have sufficient funds available to meet our obligations and our development efforts may be negatively impacted. Moreover, even if we have sufficient funds, these obligations could materially reduce the economic value of abdakibart (AVTX-009), adversely affect margins, and reduce our ability to fund other programs.

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

Periodic maintenance and annuity fees on any issued patent are due to be paid to the U.S. Patent and Trademark Office ("USPTO"), and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse in complying with any of these requirements can often be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors or collaborators fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business. In addition, we rely on third-party service providers and outside counsel for certain patent functions, and failures by such parties could adversely affect our rights.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business.

Third parties may infringe our or our licensors' or collaborators' patents or misappropriate or otherwise violate our or our licensors' or collaborators' intellectual property rights. In the future, we or our licensors or collaborators may initiate legal proceedings to enforce or defend our or our licensors' or collaborators' intellectual property rights, to protect our or our licensors' or collaborators' trade secrets or to determine the validity or scope of intellectual property rights that we license, own or control. Also, third parties may initiate legal proceedings against us or our licensors or collaborators to challenge the validity or scope of intellectual property rights we license, own or control. These proceedings can be expensive and time-consuming and many of our or our licensors' or collaborators' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaborators can. Accordingly, despite our or our licensors' or collaborators' efforts, we or our licensors or collaborators might not prevent third parties from infringing or misappropriating intellectual property rights we license, own or control, particularly in countries where the laws might not protect those rights as fully as in the United States. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in a patent infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid, unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that we or our licensors' or collaborators' patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our or our licensors' or collaborators' patents at risk of being invalidated, held unenforceable or interpreted too narrowly to cover our technology, which could negatively impact our ability to commercialize our product candidate. Even if we prevail, litigation may be costly and could delay our development or commercialization plans.

Third party pre-issuance submission of prior art to the USPTO, or opposition, derivation, reexamination, *inter partes* review or interference proceedings, or other pre-issuance or post-grant proceedings in the United States or other jurisdictions provoked by third parties or brought by us or our licensors or collaborators may be necessary to determine the priority of inventions with respect to our or our licensors' or collaborators' patents or patent applications. These proceedings can also be used to determine other critical issues, such as the validity of patents based on prior art that was not previously raised or considered during prosecution. An unfavorable outcome in a USPTO proceeding or other similar proceeding in foreign countries could require us or our licensors or collaborators to cease using the related technology and could, therefore, negatively impact our ability to commercialize our product candidates, or to attempt to license rights to it from the prevailing party.

Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license on commercially reasonable terms or at all. Even if we or our licensors or collaborators obtain such a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators. In addition, if the breadth or strength of protection provided by our or our licensors' or collaborators' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Even if we successfully defend such litigation or USPTO proceeding, we may incur substantial costs and could result in business disruption that distracts our management and other employees. We could be found liable for monetary damages, including treble damages and attorneys' fees if a court rules that we are found to have willfully infringed a third party patent.

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 warrants or shares of our common stock. In addition, we could be required to redesign our product candidates, use alternative manufacturing processes, enter into costly licenses, or stop development or commercialization altogether.

Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Though we seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties, as well as by entering into confidentiality and invention or patent assignment agreements with our employees and consultants, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we might not be able to obtain adequate remedies for such breaches. Also, trade secret protection only lasts as long as the trade secret is kept secret, an extremely high burden. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult to prove, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to enforce trade secret protections. If a competitor lawfully and without breach of a confidentiality obligation obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Certain aspects of biologic development and manufacturing may be difficult to maintain as trade secrets once disclosed in regulatory submissions, publications, or collaborations.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time-consuming, and inherently uncertain. 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 and our licensors' or collaborators' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of U.S. patents, once obtained. Depending on decisions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensors' or collaborators' ability to obtain new patents or to enforce existing patents and patents that we and our licensors or collaborators may obtain in the future. Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents. In addition, the America Invents Act includes the first-to-file provisions, which increases the uncertainties and costs surrounding the prosecution of our or our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents. Future changes in patent law could have a material adverse effect on our business and financial condition and could weaken our patent protection.

In particular, evolving standards relating to patent eligibility, obviousness, written description, enablement, claim construction, and the availability and use of post-grant proceedings could make it more difficult to obtain or enforce patents covering antibodies, biologics, and methods of treatment.

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

Filing, prosecuting, enforcing and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our or our licensors' or collaborators' intellectual property rights in some countries outside the United States can be less extensive than those in the United States. Differences in foreign patent laws, examination standards, and enforcement practices may reduce the likelihood of obtaining meaningful claims or effective remedies in certain jurisdictions. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we and our licensors or collaborators might not be able to prevent third parties from practicing our and our licensors' or collaborators' inventions in all countries outside the United States, or from selling or importing products made using our and our licensors' or collaborators' inventions in and into the United States or other jurisdictions. Competitors may use our and our licensors' or collaborators' technologies in jurisdictions where we or our licensors or collaborators have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we and our licensors or collaborators have patent protection, but in countries where patent enforcement is not as strong as that in the United States. These products may compete with our product candidates and our and our licensors' or collaborators' patents or other intellectual property rights might not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us and our licensors or collaborators to stop the infringement of our and our licensors' or collaborators' patents or marketing of competing products in such countries in violation of our and our licensors' or collaborators' proprietary rights generally. Proceedings to enforce our and our licensors' or collaborators' patent rights in any of these foreign jurisdictions could result in substantial costs and divert our and our licensors' or collaborators' efforts and attention from other aspects of our business, could put our and our licensors' or collaborators' patents at risk of being invalidated or interpreted narrowly and our and our licensors' or collaborators' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors or collaborators. We or our licensors or collaborators might not prevail in any lawsuits in foreign jurisdictions that we or our licensors or collaborators initiate and the damages or other remedies awarded, if any, might not be commercially meaningful.

The requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability and specifically requires a detailed description of medical uses of a claimed drug. Furthermore, generic or biosimilar drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' or collaborators' patents, requiring us or our licensors or collaborators to engage in complex, lengthy and costly litigation or other proceedings. Generic or biosimilar drug manufacturers may develop, seek approval for, and launch biosimilar versions of our products. Certain countries, including India and China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors or collaborators may have limited remedies if patents are infringed or if we or our licensors or collaborators are compelled to grant a license to a third party, which could materially diminish the value of those patents in these foreign countries. Such a scenario could limit our potential revenue opportunities. Geopolitical events, sanctions, trade restrictions, or changes in national policies may further limit our ability to obtain, maintain, or enforce intellectual property rights in certain jurisdictions. Accordingly, our and our licensors' or collaborators' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

Risks Related to Employee Matters and Managing Our Growth

If we fail to attract and keep management and other key personnel, as well as our board members, we may be unable to develop our product candidates or otherwise implement our business plan.

Our success will depend on the retention of our directors and members of our management and leadership team including Dr. Garry A. Neil, Chief Executive Officer and President, as well as other key scientific, clinical, regulatory and operational personnel and on our ability to continue to attract and retain highly skilled and qualified personnel. We might face challenges to employee retention and attraction due to our reliance and focus on abdakibart (AVTX-009) and our limited pipeline breadth. In addition, from time to time, there may be changes to our executive management team resulting from the hiring or departure of other executives, which could disrupt our business. The loss of one or more of our executive officers or key associates could have a serious adverse effect on our business prospects, financial condition and results of operations.

To continue to execute our business strategy, we must be able to attract and retain highly skilled personnel. We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses.

Our reliance on abdakibart (AVTX-009) as our lead and only clinical-stage asset might make the attraction of personnel who may be concerned with employment exposure due to one principal product candidate more difficult. Additionally, our lack of experience with indications in dermatology might also make the attraction of personnel more difficult. Our industry has experienced a high rate of turnover of management personnel in recent years.

As such, we could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. In addition, our limited financial resources may hinder our ability to attract and retain competent personnel. Many of the other biotechnology and pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we have. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than that which we have to offer. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will impede significantly our ability to implement our business strategy and achieve our business objectives. There can be no assurance that we will retain the services of any of our directors, officers or employees, or attract or retain additional senior managers or skilled employees when and as needed. Furthermore, we do not intend to carry key person insurance with respect to any of such individuals or, if obtained, such insurance may not be sufficient to offset the loss of any such individual.

We may encounter difficulties in managing our growth, including the focus on abdakibart (AVTX-009) and the resources necessary for its development, and expanding our operations successfully.

As we seek to advance our product candidates through clinical trials, we will need to expand our development, regulatory, manufacturing, administrative, marketing and sales capabilities or contract with third parties to provide these capabilities for us. Considering our near-term focus on the progression of the LOTUS Phase 2 Trial of abdakibart (AVTX-009) in hidradenitis suppurativa, we will need to increase our research and development infrastructure. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Any future growth will impose significant added responsibilities on members of management including increased demands on our limited internal infrastructure and systems. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth efficiently and effectively. To that end, we must be able to manage our product development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. The hiring, training and integration of new employees may be more difficult, costly and/or time-consuming for us because we have fewer resources than a larger organization. We might not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully developing our product candidates and growing our company or could result in operational inefficiencies, compliance failures or delays.

Our Chief Executive Officer has interests in the development of AVTX-006 pursuant to a royalty agreement that may conflict with interests of stockholders.

Entities affiliated with Dr. Garry Neil, our Chief Executive Officer, are parties to a Royalty Agreement with us relating to AVTX-006, a program we are no longer developing. The Royalty Agreement was entered into in July 2019 and we assumed the agreement in the Aevi Merger. The Investors will be entitled to an aggregate amount equal to a low-single digit percentage of the aggregate net sales of AVTX-006 products. At any time beginning three years after the date of the first public launch of AVTX-006 product, we may exercise, at our sole discretion, a buyout option that terminates any further obligations under the Royalty Agreement in exchange for a payment to the Investors of an aggregate of 75% of the net present value of the royalty payments. As a result of this arrangement, the interests of Dr. Neil with respect to our development programs may conflict with the interests of our stockholders. Dr. Neil could make substantial profits as a result of opportunities related to AVTX-006, which may result in him having more interest in advancing programs related to AVTX-006 as opposed to our other pipeline programs. In addition, there would be a conflict of interest if the Company determines to exercise its buyout rights under the Royalty Agreement, the exercise of which would be subject to certain approvals including by our Audit Committee and a majority of our independent directors in accordance with applicable corporate governance requirements.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. We may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. In addition, we may be subject to claims that former employees, collaborators, or other third parties of ours have an ownership interest in our patents or other intellectual property. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in obtaining or enforcing such an agreement with each party who in fact develops intellectual property that we regard as our own. We could be subject to ownership disputes arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these claims.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license might not be available on commercially reasonable terms or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management and key personnel from their core responsibilities.

We or the third parties upon whom we depend may be adversely affected by unforeseen global events, natural disasters, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Unforeseen global events, such as macroeconomic conditions, outbreaks of violence, or geopolitical instability could adversely impact our business. Such conflicts could lead to sanctions, embargoes, supply shortages, regional instability, geopolitical shifts, cyberattacks, other retaliatory actions, and adverse effects on macroeconomic conditions, currency exchange rates, and financial markets, which could adversely impact our operations and financial results, as well as those of third parties with whom we conduct business.

Additionally, any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics or pandemics, power shortage, telecommunication failure or other natural or man-made accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Natural disasters or pandemics could further disrupt our operations, and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure our investors that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities or the manufacturing facilities of our third-party contract manufacturers are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws of the FDA and other similar foreign regulatory authorities, provide true, complete and accurate information to the FDA and other similar foreign regulatory authorities, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the U.S. and similar foreign fraudulent misconduct laws or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the U.S., our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and 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.

Risks Related to our Stock, Charter and Bylaws

The price of our common stock could be subject to rapid and substantial volatility. Such volatility, including any stock run-ups, may be unrelated to our actual or expected operating performance and financial condition or prospects, making it difficult for prospective investors to assess the rapidly changing value of our common stock. Volatility in our common stock price may subject us to securities litigation or regulatory scrutiny.

The market for our common stock may have, when compared to seasoned issuers, significant price volatility and we expect that the price of our shares of common stock may continue to be more volatile than that of a seasoned issuer for the indefinite future.
As a relatively small-capitalization company with a relatively small public float, we may experience greater share price volatility, extreme price run-ups, lower trading volume, and less liquidity than large-capitalization companies.
In particular, our common stock may be subject to rapid and substantial price volatility, low volumes of trades, heightened price sensitivity to individual transactions, and large spreads in bid and ask prices.

The market price for our common stock may be influenced by many factors, including:

- Results of our clinical trials. Including topline or preliminary data and preclinical studies, and the results of trials of our competitors or those of other companies in our market sector;
- Our ability to enroll patients in our future clinical trials;
- Our ability to obtain and maintain regulatory approval of any of our current or future product candidates or additional indications thereof, including the timing, scope and conditions of such approvals or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- Regulatory or legal developments in the United States and foreign countries;
- Changes in the structure of healthcare payment systems;
- The success or failure of our efforts to develop, acquire, or license any of our current or future product candidates;
- Innovations, clinical trial results, product approvals and other developments regarding our competitors;

- Announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments;
- Manufacturing, supply, or distribution delays or shortages;
- Any changes to our relationship with any manufacturers, suppliers, collaborators or other strategic partners;
- Achievement of expected product sales and profitability or failure to achieve anticipated milestones;
- Variations in our financial results or development timelines or those of companies that are perceived to be similar to us, including variations from expectations of securities analysts or investors;
- Market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations;
- Trading volume of our common stock;
- An inability to obtain additional funding on acceptable terms, or at all;
- Sales of our stock by us, our insiders or our stockholders, as well as the anticipation of lock-up releases or expiration of market stand-off or lock-up agreements;
- General economic, industry, geopolitical and market conditions, such as military conflict or war, inflation and financial institution instability, or pandemic or epidemic disease outbreaks, many of which are beyond our control;
- Additions or departures of senior management, directors or key personnel;
- Intellectual property, product liability or other litigation against us or our inability to enforce our intellectual property;
- Changes in our capital structure, such as future issuances of securities and the incurrence of additional debt; and
- Changes in accounting standards, policies, guidelines, interpretations or principles or their application to our business.

The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock. Such volatility, including any stock run-ups, may be unrelated to our actual or expected operating performance and financial condition or prospects, making it difficult for prospective investors to assess the rapidly changing value of our common stock. As a result of this volatility, investors may experience losses on their investment in our common stock. A decline in the market price of our common stock also could adversely affect our ability to issue additional common stock or other securities and our ability to obtain additional financing in the future on favorable terms.

In addition, if the trading volumes of our common stock are low, persons buying or selling in relatively small quantities may easily influence the price of our common stock over short or extended periods of time. This low volume of trades could also cause the price of our common stock to fluctuate greatly, with large percentage changes in price occurring in any trading day session. Holders of our common stock may also not be able to readily liquidate their investment or may be forced to sell at depressed prices due to low volume trading. No assurance can be given that a higher volume active market in our common stock will develop or be sustained. If a higher volume active market does not develop, holders of our common stock may be unable to readily sell the shares they hold or may not be able to sell their shares at all.

To the extent that a secondary market for the Series C non-voting convertible preferred stock or the warrants develops, we believe that the market price of the Series C non-voting convertible preferred stock and the warrants would be significantly affected by the market price of our common stock and overall market conditions. No assurance can be given that an active market in our Series C non-voting convertible preferred stock or the warrants will develop or be sustained. If an active market does not develop, holders of our Series C non-voting convertible preferred stock or the warrants may be unable to readily sell the securities they hold or may not be able to sell their securities at all at prices they consider acceptable.

In addition, in the past, plaintiffs have often initiated securities class action litigation against a company following periods of volatility in the market price of its securities.
We may, in the future, be the target of similar litigation regardless of the merits of such claims. Securities litigation could result in substantial costs and liabilities to the Company and could divert our management's attention and resources.

Conversion of the outstanding shares of our preferred stock will dilute the percentage ownership of the holders of our common stock.

The non-voting convertible preferred stock outstanding at December 31, 2025 is convertible into an aggregate of approximately 18.8 million shares of our common stock, subject to certain beneficial ownership limitations. The conversion of those shares will cause the percentage of voting ownership of our existing stockholders to be significantly diluted, even though the economic interest will not change because the value of shares issuable upon conversion was reflected in the purchase price of the preferred stock and such dilution may adversely affect the market price of our common stock.

Future sales and issuances of shares of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect to need to raise additional capital in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, and expanded research and development activities. To raise capital, we expect to sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by such sales and new investors could gain rights, preferences and privileges senior to our existing stockholders.

We are authorized to grant equity awards, including stock grants and stock options, to our employees, directors and consultants. As of December 31, 2025, there were 327,806 shares available for future issuance under the Fourth Amended and Restated 2016 Equity Incentive Plan (the "2016 Fourth Amended Plan"). During the term of the 2016 Fourth Amended Plan, the share reserve will automatically increase on the first trading day in January of each calendar year, by an amount equal to 5% of the total number of outstanding shares of our common stock and Series C Preferred Stock (determined on an as-converted stock basis) plus all outstanding prefunded warrants to acquire shares of common stock (if any) as of December 31st of the preceding calendar year. On January 1, 2026, under these terms, an additional 1,865,256 shares were made available for issuance. In addition, as of December 31, 2025, there were 533,159 shares available for future issuance under the 2016 Employee Stock Purchase Plan (the "ESPP"). On January 1 of each calendar year, the aggregate number of shares that may be issued under the ESPP automatically increases by a number equal to 1% of the Company's outstanding shares of our common stock and Series C Preferred Stock (determined on an as-converted basis) plus all outstanding prefunded warrants to acquire shares of common stock (if any), as of December 31st of the preceding calendar year. On January 1, 2026, under these terms, the number of shares available for issuance under the ESPP increased by 373,051 shares. Future issuances, as well as the possibility of future issuances, under the 2016 Fourth Amended Plan or the ESPP or other equity incentive plans could cause the market price of our common stock to decrease.

If we are not able to comply with the applicable continued listing requirements or standards of The Nasdaq Stock Market, Nasdaq could delist our common stock.

Our common stock is currently listed on The Nasdaq Stock Market. In order to maintain that listing, we must satisfy minimum financial and other continued listing requirements and standards, including those regarding director independence and independent committee requirements, minimum stockholders' equity, a minimum closing bid price of $1.00 per share, and certain corporate governance requirements. There can be no assurances that we will be able to comply with the applicable listing standards.

In the event that our common stock is delisted from The Nasdaq Stock Market and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further. Also, it may be difficult for us to raise additional capital if we are not listed on an exchange on a timely basis or at all.

A delisting would also likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we may take actions to restore our compliance with The Nasdaq Stock Market's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below The Nasdaq Stock Market minimum bid price requirement or prevent non-compliance with The Nasdaq Stock Market's listing requirements.

Sales of a significant number of shares of our common stock in the public markets, or the perception that such sales could occur, could depress the market price of our common stock.

We expect to need to raise capital to fund our operations in the future and may do so through the sale of common stock or securities convertible into shares of common stock in registered offerings, at-the-market ("ATM") programs, private placements, or other financings. Sales of a substantial number of shares of our common stock in the public markets could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities on favorable terms, or at all. Sales of shares of common stock or common stock equivalents also may be offered in private placements, and these sales also may have a depressive effect on the market for our shares of common stock due to the delayed issuance of these shares into the public market. Further, as additional shares of our common stock become available for resale in the public market resale registration and subsequent selling, and otherwise, the supply of our common stock will increase, which could decrease its price. We cannot predict the effect that future sales of our common stock or common stock equivalents would have on the market price of our common stock.

The non-voting convertible preferred stock outstanding at December 31, 2025 is convertible into an aggregate of approximately 18.8 million shares of our common stock, subject to certain beneficial ownership limitations and other terms and conditions. The sale of a substantial number of shares of our securities in the public market, or the perception that such sales may occur, could adversely affect the price of our common stock on the Nasdaq Capital Market and could increase volatility and reduce liquidity. We cannot predict the effect, if any, that market sales of those shares of common stock or the availability of those shares of common stock for sale will have on the market price of our common stock or on investor perception regarding dilution.

In addition, in the future, we may also issue shares of our common stock in connection with investments or acquisitions or pursuant to strategic collaborations, licensing transactions, or other business development activities. The amount of shares of our common stock issued in connection with an investment or acquisition could substantially increase our shares of common stock outstanding, which could adversely affect the price of our common stock on the Nasdaq Capital Market.

Unstable global economic and geopolitical conditions may have serious adverse consequences on our business, financial condition, stock price and results of operations.

As widely reported, global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the potential for significant changes in U.S. policies or regulatory environment given the new administration, military conflict, including the ongoing conflicts between Russia and Ukraine, and in the Middle East, terrorism, or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including in Ukraine, may also continue to adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn and sector-specific rotations away from small-cap biotechnology companies. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, may reduce capacity, prioritize other customers, or increase prices which could directly affect our ability to attain our operating goals on schedule and on budget.

Separately, changes in U.S. federal policy that affect the geopolitical landscape could give rise to circumstances outside our control that could have negative impacts on our business operations. In 2025, the United States imposed significant tariffs on imports from other countries, including a baseline tariff of 10% on imports into the United States and higher tariffs on multiple designated countries (including the EU Member States, China, Canada, and Mexico), such as “reciprocal” tariffs at varying rates. Such tariffs have prompted retaliatory measures from several countries, which may further escalate. On April 9, 2025, the U.S. announced a temporary pause on its tariffs applicable to many countries, while increasing the tariffs applicable to imports from China. In addition, the current U.S. administration has expressed an intent to impose tariffs on pharmaceutical imports, with the stated policy objective of reshoring pharmaceutical manufacturing to the United States. Among other means, such tariffs may be imposed by the United States under Section 232 of the Trade Expansion Act of 1962, as amended, pursuant to which the U.S. Department of Commerce recently initiated an investigation to determine the effects of importing pharmaceuticals and pharmaceutical ingredients on national security. The new U.S. administration has threatened to continue to broadly impose tariffs, which could lead to corresponding punitive actions by the countries with which the U.S. trades.
Historically, tariffs have led to increased trade and political tensions, between not only the U.S. and China, but also between the U.S. and other countries in the international community. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods.

Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or results of operations including through higher input costs, delays in logistics, or reduced availability of materials and services used by our third-party manufacturers and clinical trial vendors. We are continuing to monitor global capital markets and assessing the potential impact of these factors on our business.

Our business is subject to risks arising from pandemics and epidemic diseases.

Public health crises such as pandemics or similar outbreaks could adversely impact our business and the operations of the third parties on which we rely. Infectious diseases may also affect research activities and employees of third-party CROs located in affected geographies that we rely upon to carry out our clinical trials. In addition, the patient populations that our lead and other core product candidates target may be particularly susceptible to infectious diseases or its variants, which may make it more difficult for us to identify patients able to enroll in our clinical trials and may impact the ability of enrolled patients to complete any such trials. Any negative impact that any future infectious disease spread has to patient enrollment or treatment, or the execution of our product candidates could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and have a material adverse effect on our financial results and liquidity.

Additionally, timely enrollment in clinical trials is dependent upon clinical trial sites which will be adversely affected by global health matters, such as pandemics. Some factors from any public health crisis that may delay or otherwise adversely affect enrollment in the clinical trials of our product candidates, as well as our business generally, include:

- The potential diversion of healthcare resources away from the conduct of clinical trials to focus on pandemic concerns;
- Limitations on travel that could interrupt key trial and business activities;
- The potential negative effect on the operations of our third-party manufacturers and the supply chain for our product candidates;
- Interruptions in global shipping affecting the transport of clinical trial materials; and
- Business disruptions caused by potential workplace, laboratory and office closures or workforce unavailability.

Any future pandemic or epidemic disease outbreak could also potentially further affect the business of the FDA or other foreign regulatory authorities, which could result in delays in meetings related to our planned clinical trials, as well as have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed or causing capital to be less available to small-cap biotechnology companies.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our securities prices and trading volume could decline.

The trading market for our securities depends in part on the research and reports that securities or industry analysts publish about us or our business. We currently have limited, and might not sustain, research coverage by securities and industry analysts. If we do not sustain coverage of ourselves, the trading price for our securities would be negatively impacted and volatility could increase. If the securities and industry analysts are unable to predict accurately the cost of advancing our pipeline, that could result in our reported costs being different than expectations, which could negatively affect our stock price. If one or more of the analysts who covers us downgrades our securities or publishes inaccurate or unfavorable research about our business, our securities prices would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our securities could decrease, which could cause our securities prices and trading volume to decline and impair our ability to access the capital markets.

Because we do not intend to declare cash dividends on our shares of common stock in the foreseeable future, stockholders must rely on appreciation of the value of our common stock for any return on their investment.

We have never declared or paid cash dividends on our common stock. The continued operation and expansion of our business will require substantial funding. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. Accordingly, we do not anticipate that we will pay any cash dividends on shares of our common stock for the foreseeable future. Consequently, stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any gains on their investment. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

Changes in tax law may adversely affect us or our investors.

The rules dealing with U.S. federal, state and local and non-U.S. taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service (the "IRS"), the U.S. Treasury Department and other taxing authorities. For example, the One Big Beautiful Bill Act (the "OBBBA"), was signed into law on July 4, 2025 and made significant changes to the U.S. federal tax law. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. These changes could subject us to additional income-based taxes and non-income taxes (such as payroll, sales, use, value-added, net worth, property, and goods and services taxes), which in turn could materially affect our financial position and results of operations.

For example, under Section 174 of the Internal Revenue Code of 1986, as amended (the "IRC"), in taxable years beginning after December 31, 2021, expenses that are incurred for research and development performed outside the U.S. will be capitalized and amortized, which may have an adverse effect on our cash flow. The OBBBA provides that for taxable years beginning after December 31, 2024, expenses that are incurred for research and development performed in the U.S. may, at the taxpayer's election, be immediately deducted or capitalized and amortized. In addition, the OBBBA provides that for taxable years beginning after December 31, 2021 and before January 1, 2025, certain eligible taxpayers generally may elect to retroactively deduct expenses for research and development performed in the U.S. in such taxable years by filing amended tax returns for such taxable years, and all other taxpayers that are not eligible to make such an election and that amortized expenses for research and development performed in the U.S. in such taxable years generally may elect to accelerate and deduct the remaining unamortized amounts of such research and development expenses (i) in the first taxable year beginning after December 31, 2024, or (ii) ratably over the two-taxable year period beginning with the first taxable year beginning after December 31, 2024. Additionally, new, changed, modified, or newly interpreted or applied tax laws could increase our customers' and our compliance, operating and other costs, as well as the costs of our products. In recent years, many such changes have been made and changes are likely to continue to occur in the future. It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be promulgated or issued under existing or new tax laws, which could result in an increase in our or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof and could adversely affect the market price of our common stock.

As we expand the scale of our business activities, any changes in the U.S. and non-U.S. taxation of such activities may increase our effective tax rate and harm our business, financial condition and results of operations. You are urged to consult your tax advisor regarding the implications of potential changes in tax laws on an investment in our common stock.

We incur increased costs and obligations as a result of being a public company.

As a public company, we are required to comply with certain additional corporate governance and financial reporting practices and policies and are subject to heightened public-company scrutiny, including by regulators, stock exchanges, investors, and proxy advisory firm. As a result, due to compliance requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Protection Act, the listing requirements of the Nasdaq, and other applicable securities rules and regulations, we have and will continue to incur significant legal, accounting, and other expenses and may be required to implement additional policies, procedures, and internal controls. The Exchange Act requires, among other things, that we file annual, quarterly, and current reports with respect to our business and operating results with the SEC. We are also required to ensure that we have the ability to prepare financial statements and other disclosures that are fully compliant with all SEC reporting requirements on a timely basis and to maintain effective disclosure controls and procedures and internal control over financial reporting. Compliance with these rules and regulations has increased and may continue to increase our legal and financial compliance costs, make some activities more difficult, time-consuming, or costly, and increase demand on our systems and resources.

In addition, we may be required to incur significant expenses and devote substantial management effort to maintain appropriate public company governance practices, including board and committee composition, executive compensation practices, stockholder engagement, and compliance with evolving SEC and Nasdaq rules. If we fail to maintain adequate processes and resources to satisfy our reporting obligations, or if our reporting is delayed, incomplete, or inaccurate, we could be subject to regulatory investigations or enforcement actions, securities litigation, reputational harm, and a decline in the trading price of our common stock.

Our amended and restated certificate of incorporation provides that unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum 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, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the exclusive forum for 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 pursuant to the DGCL, our amended and restated certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine.

Any person or entity purchasing or otherwise acquiring any interest in any of our securities will be deemed to have notice of and consented to these provisions. These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum of its choosing for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees and may result in increased costs to a stockholder to bring a claim.

If a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and other employees.

This choice of forum provision does not preclude or contract the scope of exclusive federal or concurrent jurisdiction for any actions brought under the Securities Act or the Exchange Act. Accordingly, our exclusive forum provision will not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would benefit our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and third amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These provisions include:

- Authorizing the issuance of "blank check" preferred stock, the terms of which we may establish and shares of which we may issue without stockholder approval;
- Prohibiting cumulative voting in the election of directors, which would otherwise allow for less than a majority of stockholders to elect director candidates;
- Prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- Eliminating the ability of stockholders to call a special meeting of stockholders; and
- Establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under the DGCL, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction or the transaction otherwise satisfies statutory exceptions. Any provision of our amended and restated certificate of incorporation or third amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change of control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our securities and the marketability of our common stock.

The rights associated with our outstanding Series D and Series E preferred stock may concentrate control of our Board of Directors and could adversely affect the interests of holders of our common stock.

We have issued one share of Series D Preferred Stock and one share of Series E Preferred Stock to two institutional investors that each carry the right to designate one member of our Board of Directors. For so long as the Series D and Series E preferred stock remains outstanding, the Series D holder and the Series E holder shall also have the right to appoint one non-voting observer to the Board of Directors. This preferred stock was issued solely for governance purposes and does not represent a material economic interest in our Company. As a result, the holder of this preferred stock is able to exercise significant influence over the composition of our Board of Directors that is disproportionate to its economic ownership of our equity and, in turn, may influence our strategic direction and governance practices.

The directors designated by the holders of this preferred stock may have interests that differ from, or conflict with, our interests or our common stockholders generally. The presence of a director appointed by a particular investor could affect deliberations of the Board of Directors and decision-making, including with respect to strategic transactions, financings, executive compensation, or other matters requiring Board of Directors approval.

In addition, this governance structure could discourage or delay a change of control of our Company or other transactions that our common stockholders may otherwise view as favorable by affecting third-party perceptions of governance, decision-making dynamics, or deal certainty.

The existence of this preferred stock and its associated director designation rights may also be viewed negatively by investors or proxy advisory firms, could reduce the perceived independence of our Board of Directors, and may adversely affect the market price of our common stock. The rights associated with our outstanding Series D and Series E preferred stock to designate a director may impair Nasdaq board independence and discourage or delay a change of control, which could adversely affect holders of our common stock. If the preferred stockholders continues to hold these rights for an extended period, holders of our common stock may have limited ability to influence Board of Directors composition through traditional stockholder voting mechanisms.

General Risk Factors

Our business and operations could suffer in the event of information technology systems and infrastructure failures, cyber-attacks or deficiencies in our cyber-security.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, research data, our proprietary business information and that of our suppliers, technical information about our product candidates, clinical trial plans and employee records. Similarly, our third-party providers (including CROs, CMOs, cloud service providers, collaboration and productivity platforms, payroll and HR providers, and other vendors)possess certain of our sensitive data and confidential information. The secure maintenance of this information is critical to our operations and business strategy. Despite the implementation of security measures, our internal information technology systems and infrastructure, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, ransomware, cyber fraud, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, including, denial-of-service attacks, business email compromises, social engineering (including phishing attacks), theft, fraud and subsequent misuse of employee credentials, as well as wrongful conduct by persons inside our organization, insiders at third-party service providers, or persons with access to systems inside our organization. The risk of a cybersecurity incident, data breach or other disruption, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased and as remote work, cloud-based services, and vendor-connected systems expand our potential attack surface. These attacks and activity are also being facilitated or enhanced by evolving technologies, including artificial intelligence.

Although we have data security measures in place designed to protect personal data, sensitive data and our systems, techniques used to obtain unauthorized access or to sabotage systems and data change frequently and often are not recognized until launched against a target. It is also possible that, due to the surreptitious nature of certain data breaches and other cybersecurity incidents, such incidents may remain undetected for an extended period, which may exacerbate harm to the company. We cannot ensure that our privacy and security measures will not be breached or otherwise fail to protect sensitive information or prevent disruption of our operations, including as a result of inadvertent disclosures through technological or human error (including employee or service provider error), or malfeasance. Unauthorized individuals may acquire or obtain unauthorized access to sensitive information. Data breaches, failures of our privacy or security measures, inadvertent disclosures, disruptions of our services, and other cybersecurity incidents could result in serious harm to our reputation, our business might suffer, and we could incur serious liability and other expenses related to litigation (such as damages associated with breach-of-contract claims), penalties for violation of applicable laws or regulations, costly litigation or government investigations, and significant costs for remediation and remediation efforts to prevent future occurrences (including forensic investigations, notification costs, credit monitoring, business interruption, increased cybersecurity controls, and vendor replacement costs). The harm associated with these negative results is likely to be exacerbated if the affected information is personally identifiable or includes sensitive health, genetic, or clinical trial-related data.

Like others in our industry, we and our vendors have experienced threats and cybersecurity incidents relating to our information technology systems and infrastructure. Attempts to disrupt or gain unauthorized access to our and our third-party vendors' information systems from malicious third parties or insider threats may incorporate widely varying and frequently changing tactics, which may be enhanced or facilitated by artificial intelligence. Any such cybersecurity incident or data breach could compromise our networks and the information stored there could be accessed, publicly disclosed, encrypted, lost, or stolen. Any such access, inappropriate disclosure of confidential or proprietary information or other loss of information, including a cybersecurity incident or data breach at third-party providers, could result in legal claims or proceedings, liability or financial loss under laws that protect the privacy of personal information, disruption of our operations or the development of our pipeline assets and damage to our reputation, which could adversely affect our business. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data and could jeopardize the integrity of our trial results or require us to repeat certain trial activities. Furthermore, as a result of cyber-attacks we may inadvertently misappropriate assets that we may not be able to fully recover or may be accused of misappropriation or unauthorized access based on compromised credentials or systems. Our contracts may 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 privacy and data security obligations.

Further, although we maintain cyber liability insurance, this insurance may not provide adequate coverage against potential liabilities related to any experienced cybersecurity incident or data breach and may be subject to exclusions, sublimits, deductibles, coverage disputes, or premium increases.

Any cybersecurity incident or disruption, including those affecting third parties on which we rely, could also impair our ability to comply with applicable reporting obligations and could expose us to regulatory scrutiny, enforcement actions, and securities litigation.

We may be subject to future litigation against us, which could be costly and time-consuming to defend.

We may become subject, from time to time, to legal proceedings and claims that arise in the ordinary course of business such as claims brought by our collaborators in connection with commercial disputes, or employment claims made by our current or former employees as well as claims relating to intellectual property, privacy and data security, contracts, securities laws, product development activities, or other matters. Litigation might result in substantial costs and may divert management's attention and resources, which might seriously harm our business, overall financial condition, and operating results. Insurance might not cover such claims, might not provide sufficient payments to cover all the costs to resolve one or more such claims, and might not continue to be available on terms acceptable to us. A claim brought against us that is uninsured or underinsured could result in unanticipated costs, thereby reducing our operating results and leading analysts or potential investors to reduce their expectations of our performance, which could reduce the trading price of our stock.

We may be subject to numerous and varying privacy and security laws, and our failure to comply could result in penalties and reputational damage.

We collect and process sensitive information, including confidential business information and information associated with clinical trials including in some limited cases, personal information and sensitive health-related data.

As such, we might be subject to certain laws and regulations governing the privacy and security of personal information, including regulations pertaining to health information. The legislative and regulatory landscape for privacy and data security continues to evolve, and there has been an increasing focus on privacy and data security issues that may affect our business. In the United States, numerous federal and state privacy and data security laws and regulations that govern the collection, use, disclosure, and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws, and federal and state data security laws. Each of these laws, , such as the Health Insurance Portability and Accountability Act ("HIPAA"), is subject to extensive interpretations by courts and government agencies, creating complex compliance issues for us. If we fail to comply with applicable laws and regulations, we could be subject to lawsuits, penalties, or sanctions, consent decrees, audits, and reputational harm.

At the federal level, failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business and the cost of available tools to improve security and reduce vulnerabilities. The HHS Office for Civil Rights, which enforces HIPAA, also remains active in its enforcement of the law. Additionally, state attorneys general may bring civil actions seeking either injunctions or damages in response to violations of HIPAA that threaten the privacy of state residents and private litigants may assert state-law claims based on the same underlying conduct.

Privacy and data security have become an area of emphasis for some state legislatures, many of which have passed comprehensive state privacy laws. For example, California enacted the California Consumer Privacy Act("CCPA"), which creates individual privacy rights for California consumers (as the term "consumers" is defined by the law) and increases the privacy and security obligations of entities handling certain personal data. The CCPA requires covered companies to provide certain disclosures to consumers about their data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. While there is currently an exception for protected health information that is subject to HIPAA as well as for data collected in the context of clinical trials, the CCPA may impact our business activities. Following California's lead, more than 19 additional states, including Virginia, Colorado, Connecticut, New Jersey, and New Hampshire, have adopted comprehensive privacy laws. While these laws incorporate many similar concepts to those in the CCPA, there are also several key differences in the scope, application, and enforcement of the laws that will change the operational practices of regulated businesses. These laws will, among other things, impact how regulated businesses collect and process personal sensitive data, conduct data protection assessments, transfer personal data to affiliates, and respond to consumer rights requests. There are also states that are specifically regulating health information. For example, Washington's My Health My Data Act regulates the collection and sharing of health information and has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. In addition, other states have proposed and/or passed legislation that regulates the privacy and/or security of certain specific types of information. For example, a small number of states, including Illinois and Texas, have passed laws that regulate biometric data specifically.

State legislatures continue to pass comprehensive and industry-specific privacy and data security laws that may present compliance challenges, including privacy laws regulating health-related information. The existence of a patchwork of privacy laws in different states make our compliance obligations add complexity, variation in requirements, restrictions and potential legal risk that requires additional investment of resources in compliance programs.

Further, these privacy laws may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. In addition to the risk associated with enforcement, compliance with and implementation of these evolving laws, rules, and regulations regarding the privacy, security and protection of personal information could result in higher compliance and technology costs for us, present challenges for our business model and could require significant changes to our policies, procedures, and data-processing practices.

There are numerous federal and state laws that generally require notice to affected individuals, regulators, and sometimes the media or credit reporting agencies in the event of a data breach impacting personal information. For example, at the federal level, HIPAA Breach Notification Rule mandates notification of breaches affecting protected health information to affected individuals and regulators under conditions set forth in the Rule. Covered entities must report breaches of unsecured protected health information to affected individuals without unreasonable delay, but not to exceed 60 days of discovery of the breach by a covered entity or its agents. Notification must also be made to HHS and, in certain circumstances involving large breaches, to the media. Business Associates must report breaches of unsecured protected health information to covered entities. All states, the District of Columbia, Guam, Puerto Rico, and the Virgin Islands have enacted data breach notification laws. These laws may impose notification obligations in addition to, or inconsistent with, the HIPAA Breach Notification Rule when a data breach implicates protected health information. In the event that we fail to detect or timely report a data breach it may be subject to significant penalties under federal and state law. In the event that we report a data breach as required by federal or state law, federal or state regulators may initiate an investigation into, and/or litigation related to, our privacy or data security practices. Private plaintiffs may also initiate costly class action litigation following a data breach.

Numerous other countries have, or are developing, laws governing the collection, use, and transmission of personal information. These laws often impose significant compliance obligations. For example, our operations involving clinical trials in the European Economic Area ("EEA") bring us within the scope of the EU General Data Protection Regulation ("EU GDPR"), as well as other national data protection legislation in force in relevant EEA Member States, which govern the collection, use, storage, disclosure, transfer, or other processing of personal data (including health data processed in the context of clinical trials) regarding individuals in the EEA. The GDPR is wide-ranging in scope and imposes additional obligations on companies that process personal information. These, include specific requirements regarding the processing of health and other sensitive data; obtaining valid consent from individuals in certain circumstances; providing expanded disclosures about data processing; implementing safeguards to ensure the security and confidentiality of personal data; limiting retention periods; and strengthening obligations around pseudonymized (i.e., key-coded) data. The GDPR also introduces mandatory breach notification obligations and requires that contractual and other measures be in place when engaging third-party service providers. In addition, the GDPR imposes strict rules on transfers of personal data out of the EEA to third countries, such as the U.S., unless a valid transfer mechanism (e.g., the European Commission's Standard Contractual Clauses, or SCCs) is in place or a derogation applies. Where we rely on the SCCs, we may also be required to carry out transfer impact assessments to evaluate whether recipients are subject to local laws that could permit government access to personal data. If we are unable to lawfully transfer personal data from the EEA to the U.S., our operations, business continuity, and financial position could be adversely affected.

We are taking steps to comply with the GDPR as appropriate and as applicable to our operations, but compliance is an ongoing and evolving process. Meeting GDPR requirements is rigorous and time-intensive, and may increase our operational costs or require changes to our business practices. Any failure to comply with the EU GDPR could lead to government enforcement actions and significant penalties against us and adversely impact our operating results. If our operations are found to violate EU GDPR requirements, we may incur substantial fines, have to change our business practices, and face reputational harm, any of which could have an adverse effect on our business. In particular, serious breaches of the GDPR can result in regulatory sanctions and administrative fines of up to €20 million or 4% of annual worldwide revenues for the preceding financial year. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR.

In addition, EEA Member States have adopted national laws to implement the GDPR that may deviate in part from the EU regulation. The GDPR also allows each Member State to introduce its own legal requirements for processing genetic, biometric, or health data. Competent authorities across Member States may also interpret and enforce GDPR obligations differently. As a result, we do not expect to operate under a uniform legal framework within the EEA. These variations may increase the complexity and cost of compliance, limit our ability to use and share personal data across jurisdictions, and affect our operational efficiency. Further, the UK data protection regime is currently independent from the EU GDPR but remains broadly aligned with it. To the extent our activities become subject to the UK GDPR in the future, we would be required to comply with obligations similar to those under the EU GDPR in relation to the processing of UK personal data. Any future divergence between the UK and EU data protection regimes could create legal uncertainty, increase compliance complexity and cost, and require us to adjust how we handle personal data in these regions.

All of these evolving compliance and operational requirements impose costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants and legal advisors, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, utilize management's time and/or divert resources from other initiatives and projects.

Any failure or perceived failure by us to comply with any applicable federal, state or foreign laws and regulations relating to data privacy and security could result in damage to our reputation, as well as proceedings or litigation by governmental agencies or other third parties, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, sanctions, awards, injunctions, penalties or judgments. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

The U.S. Congress or the current administration may make substantial changes to fiscal, tax, and other federal policies that may adversely affect our business.

Since the start of the current administration in 2025, there have been significant changes to U.S. trade, healthcare, immigration and government regulatory policy and additional changes are likely. For example, the U.S. government has imposed substantial tariffs on most countries throughout the world and has further threatened to continue to broadly impose tariffs, which could lead to corresponding punitive actions by the countries with which the U.S. trades. Changes to U.S. policy implemented by the U.S. Congress, the current administration or any new future administration have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. Although we cannot predict the impact, if any, of these changes to our business, they could adversely affect our business, including by increasing our costs, restricting access to suppliers, vendors, or clinical trial sites, or creating delays in procurement, logistics, or regulatory interactions. Until we know what policy changes are made, whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them.

Our use of new and evolving technologies, such as artificial intelligence, may present risks and challenges that can impact our business, including by posing cybersecurity and other risks to our confidential and/or proprietary information, including personal information, and as a result we may be exposed to reputational harm and liability.

We may use, and our vendors may incorporate, artificial intelligence ("AI") both in our own development and implementation of AI and through the adoption of commercially available tools. The use of AI presents risks and challenges that could adversely affect our business, including cybersecurity, data privacy, IT, confidentiality, regulatory, legal, operational, competitive, reputational and intellectual property risks. Specifically, risks related to accuracy, bias, artificial intelligence hallucinations, discrimination, harmful content, misinformation, fraud, scams, targeted attacks (including model poisoning or data poisoning), surveillance, data leakage, environmental and other harms may flow from our development, use, or deployment of AI technologies. For example, use of certain AI tools may increase the risk of unauthorized disclosure of confidential information, compromise of proprietary intellectual property, or inadvertent inclusion of third-party intellectual property or other protected material, which could result in disputes or claims of infringement.

Additionally, government and supranational regulation related to AI is evolving and could increase the burden and cost of compliance, including through requirements related to transparency, accountability, risk management, human oversight, and data governance . For example, the EU's Artificial Intelligence Act ("AI Act") began its implementation on August 1, 2024, with a larger portion of the law scheduled to come into effect in August 2026. As currently enacted, the AI Act, which may be amended as part of the EU's Digital Omnibus, imposes significant obligations on providers and deployers of high-risk artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. The scope of requirements depends on legal and risk determinations that rely on novel legal provisions that have not yet been interpreted by courts or regulators, and non-compliance can lead to significant fines.

In the U.S., the regulatory environment is complex and uncertain. Over the past year, states have advanced, and in some cases passed, dozens of laws focusing on AI governance and regulation, including on deployment of AI in healthcare settings. At the federal level, the Trump Administration has endorsed a federal moratorium on the enforcement of state AI laws, including through a December 11, 2025, executive order on "Ensuring a National Policy Framework for Artificial Intelligence." So far, these efforts have not been successful at curtailing state action on AI regulation, contributing to a complicated legislative patchwork, which may be litigated in state and federal courts. In addition, there continues to be uncertainty regarding the application of existing federal and state legal frameworks to uses and development of AI, and legal norms and market standards regarding AI continue to evolve. For example, various federal and state regulators have issued guidance and focused enforcement efforts on the use of AI in regulated sectors. The U.S. Food and Drug Administration, for example, issued guidance on the use of artificial intelligence in medical devices, requiring detailed risk management and review processes to obtain approvals. If we develop or use AI systems that are governed by the these laws or regulations, we will need to meet higher standards of data quality, transparency, and human oversight, and we would need to adhere to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. We may also be subject to significant enforcement or litigation in the event of any perceived non-compliance.

The rapid evolution of artificial intelligence will require the application of significant resources to design, develop, test and maintain our products and services to help ensure that artificial intelligence is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. The use of certain AI technologies can also give rise to intellectual property risks, including by disclosing or otherwise compromising our confidential or proprietary intellectual property, or by undermining our ability to assert or defend ownership rights in intellectual property created with the assistance of artificial intelligence tools.

Our vendors may in turn incorporate artificial intelligence tools into their offerings, and the providers of these artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. In addition, the use of generative AI models in our internal or third-party systems may create new attack surfaces or methods for adversaries, which could impact us and our vendors. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

As part of our overall risk management process, we have established an Information Security Program (the "Program") designed to assess, identify, and manage cybersecurity risks as well as support efforts in responding to, and recovering from, cybersecurity threats and incidents.

Governance

Our Board of Directors has delegated Program oversight to the Audit Committee (the "Committee"). The Committee is composed of directors with expertise in technology, audit, finance, and compliance. The Company's Information Security Working Group ("ISWG") manages cybersecurity risks and oversees the design, implementation, and evaluation of the Program. The responsibilities of the ISWG include defining cybersecurity risk tolerance, guiding implementation of the Program, monitoring Program development and effectiveness, and validating investments in cybersecurity measures and infrastructure. Members of the ISWG include: the Chief Financial Officer, the Chief Legal Officer, the Senior Vice President of Human Resources, the Senior Vice President of Regulatory and Quality Assurance, and the Vice President of Information Technology. The ISWG meets semi-annually to review the effectiveness of the Program, discuss any new developments and potential improvements to the Program, and evaluate internal and external security-related events to determine how Avalo can take appropriate steps to mitigate such risks.

Our Vice President of Information Technology ("VP of IT"), is responsible for Avalo's enterprise-wide cybersecurity strategy, architecture, policies, processes, and controls, and is directly responsible for the day-to-day management of the Program. The individual serving in this role has over 20 years of experience with information technology and over 8 years of experience managing cybersecurity risk management programs. Our VP of IT reports to the Senior Vice President of Human Resources ("SVP of HR"). The VP of IT regularly informs the SVP of HR, and other members of the leadership team, about the Program, best practices, current cybersecurity threats, the cyber-risk landscape, and mitigation strategies. These reports include the following on an as-needed basis: updates on the Program; assessment of the Program; emerging risks or concerns; policies, procedures, and training; and risk mitigation strategies. The SVP of HR provides information technology and cybersecurity reports as necessary at meetings of management's Disclosure Committee. These reports are also communicated to the Audit Committee, as necessary.

Risk Management and Strategy

The underlying controls of our Program incorporate elements of recognized industry standards for cybersecurity and information technology, including the National Institute of Standards and Technology ("NIST") Cybersecurity Framework.

We use various tools and methodologies designed to identify, manage, and test for cybersecurity risk on a regular cadence both at the enterprise level and through our use of third-party service providers. These third parties include cybersecurity managed security service providers ("MSSPs"), consultants, advisors, and auditors, who we engage to evaluate our controls, whether through penetration testing, independent audits, or consulting on best practices to address new threats or challenges. We also engage internal auditors to audit our information technology control environment, test our information technology controls, and report to us any findings. External security service firms monitor Avalo's networks at all times, and Avalo laptops are patched frequently with up-to-date antivirus and real time threat-monitoring protection. Further, we actively engage with key vendors, industry participants, and law enforcement officials as part of our continuing efforts to evaluate and improve our Program.

As part of the Program, we maintain processes related to third-party vendor cybersecurity risk management. We review and confirm controls for vendors providing critical business services and employ quality agreements and vendor audits designed to ensure vendor compliance with our Program and applicable regulatory requirements. Further, we conduct information security assessments before onboarding new vendors and upon detection of an increase in risk profile for existing vendors. We also require our third-party service providers to meet appropriate security requirements, controls and responsibilities via additional security and privacy addenda which we include in our contracts where applicable.

As part of our Program, we maintain written information security policies, including an incident response plan. All Avalo employees and contractors are required to participate in annual security awareness training, which includes phishing simulations. Avalo employees are also trained on our written information security policies and the acceptable usage of systems, as well as procedures related to electronic record management.

Although risks from cybersecurity threats have not materially affected, and are not reasonably likely to materially affect our company, including our business strategy, results of operations, or financial condition, to date, we may, from time to time, experience threats to and security incidents related to our and our third-party vendors' information systems. For further information, refer to Section 1A, Risk Factors, for a discussion of risks related to cybersecurity and technology.

Item 2. Properties.

Our headquarters are located in Wayne (Chesterbrook), Pennsylvania, where we occupy approximately 11,000 square feet of administrative office space. The lease expires on February 28, 2027.

We believe that our existing facilities are adequate to meet our current needs, and that suitable spaces will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock is listed and publicly traded on The Nasdaq Capital Market under the symbol "AVTX."

Holders

As of March 18, 2026, there were approximately 145 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

Dividends

We have never declared or paid cash dividends on our capital stock. We intend to retain all of our available funds and future earnings, if any, to finance the growth and development of our business. We do not intend to pay cash dividends to our stockholders in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Recent Sales of Unregistered Securities

Except for sales of unregistered securities that have been previously reported by the Company in either its quarterly reports on Form 10-Q or current reports on Form 8-K, there were no sales of unregistered securities of the Company during the period covered by this report.

Equity Compensation Plans

Information regarding securities authorized for issuance under equity compensation plans is set forth in Item 12 of this report is under the section captioned "Equity Compensation Plan Information".

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 elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section in this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical stage biotechnology company fully dedicated to developing IL-1β-based treatments for immune-mediated inflammatory diseases. Our lead product candidate, abdakibart (AVTX-009), an anti-IL-1β monoclonal antibody ("mAb") is in a Phase 2 clinical trial for hidradenitis suppurativa ("HS"). We are also exploring additional opportunities to make an impact in prevalent indications that have significant remaining unmet needs.

In 2025, we were focused on executing operationally on the development of abdakibart (AVTX-009) in HS including progressing the Phase 2 clinical trial, which we refer to the Phase 2 LOTUS trial. The global study which includes approximately 250 adults with moderate to severe hidradenitis suppurativa is designed to evaluate the efficacy and safety of subcutaneous bi-weekly and monthly dosing regimens compared to placebo. Our current focus is completing the Phase 2 LOTUS trial, preparing for the anticipated topline data readout in the second quarter of 2026, and planning for our Phase 3 trial(s).

Management's primary evaluation of our success is the ability to progress its programs towards commercialization or opportunistically out-licensing rights to indications or geographies. We believe the ability to achieve the next anticipated milestone as presented in the section entitled "Business" in Item 1 of this Annual Report on Form 10-K represents our most immediate evaluation point as to the progression of our pipeline.

2025 Financial Operations Overview

As of December 31, 2025, we had $98.3 million in cash and cash equivalents and short-term investments. Net cash used in operating activities was $51.5 million for the year ended December 31, 2025. Our current cash, cash equivalents and short-term investments are expected to fund operations into 2028.

Net loss for the year ended December 31, 2025 was $78.3 million, representing a $43.1 million increase in net loss as compared to the prior year. Research and development expenses increased $25.6 million from the prior year driven by costs related to and supporting the Phase 2 LOTUS trial. General and administrative expenses increased $5.7 million from the prior year mainly due to increased stock-based compensation. These increases were offset by a $27.6 million acquired in-process research and development charge in 2024 that did not repeat. Further, we recognized $5.2 million of other expense for the year ended December 31, 2025 as compared to $33.5 million of other income in the prior year, which contributed to the increase in net loss. The other income recognized in the prior period primarily related to the accounting impact of the warrants that were issued and exercised in 2024.

We expect operating expenses to be largely consistent with 2025 through the Phase 2 LOTUS trial topline data readout expected in the second quarter of 2026, however, expenses beyond the data readout are difficult to predict given they will be highly dependent on the outcome of the trial.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

Product Revenue, net

We recognized minimal net product revenue for the year ended December 31, 2025 compared to $0.4 million for the year ended December 31, 2024, which related to a change in estimate of commercial liabilities, mainly sales returns, for the Millipred® product. Our license and supply agreement for Millipred® expired on September 30, 2023 as planned and as such there was no gross revenue recognized from sales for the years ended December 31, 2025 and December 31, 2024. We do not expect significant movement in estimates of commercial liabilities, however, if additional information becomes available, we could recognize expense (or a benefit) for differences between actuals or updated estimates to the reserves previously recognized, which could be recognized in net product revenue.

Cost of Product Sales

We recognized no cost of product sales for the year ended December 31, 2025 compared to a benefit of $0.4 million for the same period in 2024, which related to the change in an estimate of commercial liabilities for the Millipred® product. The Company ceased selling Millipred® in September 2023. We do not expect significant movement in estimates of commercial liabilities, however, if additional information becomes available, we could recognize expense (or a benefit) for differences between actuals or updated estimates to the reserves previously recognized, which could be recognized in cost of product sales.

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Nonclinical expenses	$ 824	$ 570
Clinical expenses	24,865	9,966
CMC expenses	9,657	5,106
Internal expenses:		
Salaries, benefits and related costs	8,502	6,164
Stock-based compensation expense	5,992	2,402
Other	244	229
	$ 50,084	$ 24,437

Research and development expenses increased $25.6 million for the year ended December 31, 2025 compared to the prior period. The increase was driven by increases in clinical and CMC expenses of $14.9 million and $4.6 million, respectively. Clinical expenses increased due to progress in the current year for the Phase 2 LOTUS trial in HS, including site activations, patient trial costs and clinical trial work performed by our contract research organization, as compared to trial enabling and activation activities incurred in the prior year period. CMC expenses increased due to raw material purchases and drug manufacturing activities to support the trial during the current year.

Additionally, stock-based compensation increased $3.6 million compared to the year ended December 31, 2024 due to option and restricted stock unit grants made during the second half of 2024 and in 2025, including the annual employee grants in August 2024 and January 2025, as well as headcount additions. Salaries, benefits and related costs increased $2.3 million compared to the year ended December 31, 2024 primarily due to headcount additions.

We expect research and development expenses to be largely consistent with 2025 through the Phase 2 LOTUS trial topline data readout expected in the second quarter of 2026, however, expenses beyond the data readout are difficult to predict given they will be highly dependent on the outcome of the trial.

Acquired In-Process Research and Development

In the first quarter of 2024, we acquired abdakibart (AVTX-009) through the AlmataBio Transaction (as defined in Note 3 to the consolidated financial statements included in this Annual Report on Form 10-K), resulting in us acquiring $27.6 million of in-process research and development ("IPR&D") for the year ended December 31, 2024. There was no acquired IPR&D for the year ended December 31, 2025.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the years ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Salaries, benefits and related costs	$ 6,558	$ 4,634
Legal, consulting and other professional expenses	6,786	7,096
Stock-based compensation expense	7,629	3,450
Commercial planning and marketing expenses	470	789
Other	1,457	1,272
	$ 22,900	$ 17,241

General and administrative expenses increased $5.7 million for the year ended December 31, 2025 compared to the prior year period. The increase was driven primarily by a $4.2 million increase in stock-based compensation expense due to option and restricted stock unit grants made during the second half of 2024 and in 2025, including the annual grants in August 2024 and January 2025 as well as new hire grants. Salaries, benefits and related costs increased $1.9 million compared to the year ended December 31, 2024 due to headcount additions. This increase was partially offset by a $0.3 million decrease to commercial planning and marketing as we transitioned certain third-party consulting engagements for market opportunity assessments and competitive intelligence to salaried headcount.

These increases were partially offset by a $0.3 million decrease in legal, consulting and other professional expenses compared to the prior year period related to increased expenses incurred in the prior period for accounting, reporting and consulting services incurred following the AlmataBio Transaction and concurrent private placement financing in March 2024.

We expect general and administrative expenses to be largely consistent with 2025 through the Phase 2 LOTUS trial topline data readout expected in the second quarter of 2026, however, expenses beyond the data readout are difficult to predict given they will be highly dependent on the outcome of the trial.

Other (Expense) Income, net

The following table summarizes our other (expense) income, net for the years ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Change in fair value of derivative liability	(9,520)	(2,930)
Interest income, net	4,351	3,312
Excess of initial warrant fair value over private placement proceeds	$ —	$ (79,276)
Change of fair value of warrant liability	—	121,611
Private placement transaction costs	—	(9,220)
	$ (5,169)	$ 33,497

Other expense, net was $5.2 million for the year ended December 31, 2025 compared to other income, net of $33.5 million for the prior year period ended December 31, 2024. The $38.7 million change was primarily driven by (i) the accounting impact in the prior period of the warrant liability associated with the warrants issued in the March 2024 financing that were subsequently exercised in the fourth quarter of 2024, and (ii) the change in the fair value of the derivative liability in the current period driven by changes in assumptions related to the AVTX-007 Milestones and Royalties (as defined in Note 6 to the consolidated financial statements included in this Annual Report on Form 10-K). Further, we incurred $9.2 million of private placement transaction costs in the prior year period that did not repeat in the current period, largely consisting of the placement agent fee of $7.0 million and $1.7 million fee payable upon exercise of the warrants issued in the private placement investment.

Income Tax Expense

The following table summarizes our income tax expense for the years ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Income tax expense	$ 165	$ 114

We recognized minimal income tax expense for the years ended December 31, 2025 and 2024.

Liquidity and Capital Resources, including Capital Expenditure and Cash Requirements

Since inception, we have incurred significant operating losses and negative cash flows from our operations. We have primarily funded our operations to date through sales of equity securities, out-licensing transactions and sales of assets.

For the year ended December 31, 2025, we generated a net loss of $78.3 million and negative cash flows from operations of $51.5 million. As of December 31, 2025, we had $98.3 million in cash and cash equivalents and short-term investments.

Based on our current operating plans, we expect that our existing cash, cash equivalents and short-term investments are sufficient to fund operations into 2028. We closely monitor our cash and cash equivalents and seek to balance the level of cash and cash equivalents with our projected needs to allow us to withstand periods of uncertainty relative to the availability of funding on favorable terms. We may satisfy any future cash needs through sales of equity securities under the our at-the-market program or other equity financings, out-licensing transactions, strategic alliances/collaborations, sale of programs, and/or mergers and acquisitions. There can be no assurance that any financing or business development initiatives can be realized by us, or if realized, what the terms may be. To the extent that we raise capital through the sale of equity, the ownership interest of our existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. Further, if we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we might have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates.

Uses of Liquidity

We primarily use cash to fund the ongoing development of abdakibart (AVTX-009) and costs associated with its organizational infrastructure. As of December 31, 2025, we had $98.3 million in cash and cash equivalents and short-term investments. We expect cash used in operations to be largely consistent with 2025 through the Phase 2 LOTUS trial topline data readout expected in the second quarter of 2026, however, cash used in operations beyond the data readout are difficult to predict given they will be highly dependent on the outcome of the trial.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (51,458)	$ (49,056)
Investing activities	(81,720)	356
Financing activities	14,587	175,849
Net (decrease) increase in cash and cash equivalents	$ (118,591)	$ 127,149

Net cash used in operating activities

Net cash used in operating activities was $51.5 million for the year ended December 31, 2025 and consisted primarily of net loss of $78.3 million, partially offset by net non-cash charges of $23.0 million and changes in our operating assets and liabilities of $3.8 million. The non-cash charges consisted primarily of $13.6 million in stock-based compensation and a change in the fair value of the derivative liability of $9.5 million. Changes in our operating assets and liabilities consisted primarily of a $2.6 million increase in prepaid expenses and other current assets due to our ongoing clinical work and a $6.7 million increase in accrued expenses and other liabilities primarily due to increased drug manufacturing activities as well as compensation and benefits accruals.

Net cash used in operating activities in 2024 consisted primarily of a net loss of $35.1 million and non-cash adjustments to reconcile net loss to net cash used in operating activities including the change in fair value of the warrant liability of $121.6 million, excess of initial warrant fair value over private placement proceeds of $79.3 million, acquired IPR&D of $27.6 million, $12.5 million milestone payments made to the former AlmataBio stockholders, the change in fair value of the derivative liability of $2.9 million, and stock-based compensation of $5.9 million. Prepaid expenses increased $2.9 million from December 31, 2023 due to the increased research and development activity for abdakibart (AVTX-009).

We expect cash used in operations to be largely consistent with 2025 through the Phase 2 LOTUS trial topline data readout expected in the second quarter of 2026, however, cash used in operations beyond the data readout are difficult to predict given they will be highly dependent on the outcome of the trial.

Net cash (used in) provided by investing activities

Net cash used in investing activities for the year ended December 31, 2025 consisted of $113.7 million of purchases of available-for-sale investments, partially offset by $32.0 million of proceeds from maturities of available-for-sale investments.

Net cash provided by investing activities for the year ended December 31, 2024 consisted of the cash acquired as part of the AlmataBio Transaction.

Net cash provided by financing activities

Net cash provided by financing activities for the year ended December 31, 2025 consisted of proceeds of $14.8 million from the sales of shares made pursuant to our "at-the-market" sales agreement and proceeds of $0.8 million from stock option exercises, partially offset by $0.5 million in cash paid to tax authorities related to withholding shares to satisfy RSU vesting withholding obligations on behalf of employees.

Net cash provided by financing activities for the year ended December 31, 2024 consisted of gross proceeds of $115.6 million from the private placement that closed on March 28, 2024 and $69.4 million of gross proceeds from the exercise of warrants in the fourth quarter of 2024. The increase was partially offset by $7.5 million of transaction costs paid related to the private placement and $1.7 million of transaction costs paid related to the warrant exercises.

Critical Accounting Estimates and Assumptions

In preparing the financial statements, we make estimates and assumptions that have an impact on assets, liabilities, revenue and expenses reported. These estimates can also affect supplemental information disclosed by us, including information about contingencies, risk and financial condition. We believe, given current facts and circumstances, our estimates and assumptions are reasonable, adhere to U.S. generally accepted accounting principles ("GAAP") and are consistently applied. Inherent in the nature of an estimate or assumption is the fact that actual results may differ from estimates, and estimates may vary as new facts and circumstances arise.

While our significant accounting policies are more fully described in Note 2 to the consolidated financial statements appearing at the end of this Annual Report on Form 10-K, we believe the following accounting policies are critical to the understanding of our financial condition and results.

Stock-Based Compensation

We apply the provisions of ASC 718, *Compensation—Stock Compensation*, which requires the measurement and recognition of compensation expense for all stock-based awards made to employees, including employee stock options, in the statements of operations and comprehensive loss.

For stock options issued to employees and members of the board of directors for their services, we estimate the grant date fair value of each option using the Black-Scholes option pricing model. The use of the Black-Scholes option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected term of the option, risk-free interest rates and expected dividend yields of the common stock. Additionally, the stock price on the date of grant is utilized in the Black-Scholes option pricing model. For awards subject to service-based vesting conditions, including those with a graded vesting schedule, we recognize stock-based compensation expense equal to the grant date fair value of stock options on a straight-line basis over the requisite service period, which is generally the vesting term. Forfeitures are recorded as they are incurred.

The assumptions we used to determine the fair value of stock options granted to employees and members of the board of directors are as follows:

	Year Ended December 31,					
Service-based options	**2025**			**2024**		
Expected term of options (in years)	5.00	—	6.10	5.81	—	6.25
Expected stock price volatility	99.9%	—	113.1%	113.1%	—	116.9%
Risk-free interest rate	3.73%	—	4.45%	3.70%	—	4.26%
Expected annual dividend yield	0%			0%		

Each Restricted Stock Unit ("RSU") represents one equivalent share of our common stock to be issued after satisfying the applicable continued service-based vesting criteria over a specified period. The fair value of these RSUs is based on the closing price of our common stock on the date of the grant. The compensation for RSUs is recognized on a straight-line basis over the vesting period.

Each Performance Stock Unit ("PSU") represents one equivalent share of our common stock to be issued after achievement of the performance goals specified in the grant. We estimate the fair value of our PSUs as of the grant date based upon the expected likelihood of achievement of the performance goals specified in the grant and the closing market price of our common stock on the date of grant. We recognize stock-based compensation expense over the requisite service period, if it is probable that the performance goal will be achieved.

The estimates involved in the valuations include inherent uncertainties and the application of our judgment. As a result, if factors change and we use significantly different assumptions or estimates when valuing our stock options, our stock-based compensation expense could be materially different.

Derivative Liability

In the fourth quarter of 2022, we sold our economic rights to future milestone and royalty payments for previously out-licensed assets AVTX-501, AVTX-007, and AVTX-611 to ES Therapeutics, LLC ("ES"), an affiliate of Armistice Capital LLC ("Armistice"), in exchange for $5.0 million (the "ES Transaction"). At the time of the transaction, Armistice was a significant stockholder of ours whose chief investment officer, Steven Boyd, and managing director, Keith Maher, served on our Board until August 8, 2022. The ES Transaction was approved in accordance with our related party transaction policy.

The economic rights sold include (a) rights to a milestone payment of $20.0 million upon the filing and acceptance of an NDA for AVTX-501 pursuant to an agreement with Janssen Pharmaceutics, Inc., now Johnson & Johnson Innovative Medicine ("J&J") (the "AVTX-501 Milestone") and (b) rights to any future milestone payments and royalties relating to AVTX-007 under a license agreement with Apollo AP43 Limited ("Apollo"), including up to $6.25 million of development milestones, up to $67.5 million in sales-based milestones, and royalty payments over a ten year period of a low single digit percentage of annual net sales (which percentage increases to another low single digit percentage if annual net sales exceed a specified threshold) (the "AVTX-007 Milestones and Royalties"). In addition, we waived all of our rights to AVTX-611 sales-based payments of up to $20.0 million that were payable by ES.

The exchange of the economic rights of the AVTX-501 Milestone and AVTX-007 Milestones and Royalties for cash met the definition of a derivative instrument. The fair value of the derivative liability is determined using a combination of a scenario-based method and an option pricing method (implemented using a Monte Carlo simulation). The significant inputs including probabilities of success, expected timing, and forecasted sales as well as market-based inputs for volatility, risk-adjusted discount rates and allowance for counterparty credit risk are unobservable and based on the best information available to us. Certain information used in the valuation is inherently limited in nature and could differ from J&J's and Apollo's internal estimates.

The fair value of the derivative liability as of the transaction date was approximately $4.8 million, of which $3.5 million was attributable to the AVTX-501 Milestone and $1.3 million was attributable to the AVTX-007 Milestones and Royalties. Subsequent to the transaction date, at each reporting period, the derivative liability is remeasured at fair value. As of December 31, 2025, the fair value of the derivative liability was $18.0 million, all of which was attributable to the AVTX-007 Milestone and Royalties and was classified as a non-current liability. For the year ended December 31, 2025, the $9.5 million change in fair value was recognized in other expense, net in the accompanying consolidated statements of operations and comprehensive loss.

The fair value of the AVTX-501 Milestone was deemed to be de minimis, driven by less than 1% probability of success based on our interpretation of an announcement from J&J in March 2025, noting the discontinuation of the aticaprant depression program (previously referred to as AVTX-501 by us), which was the only indication publicly disclosed, paired with a lack of commitment to an alternative indication. The fair value of AVTX-007 Milestones and Royalties was primarily driven by sales forecasts with peak annual net sales reaching $1.7 billion in atopic dermatitis, an approximate 41% probability of success, and an estimated time to commercialization of approximately 6.5 years, based on our interpretation of Apollo's September 2025 announcement that the drug met the primary endpoint in its Phase 2a clinical trial in atopic dermatitis. We estimated these unobservable inputs based on limited publicly available information and therefore could differ from J&J's and Apollo's respective internal development plans, assessments of probability of success and other inputs of our fair value calculation. Any changes to these inputs may result in significant changes to the fair value measurement. Notably, the peak annual net sales forecast (for the AVTX-007 Milestones and Royalties) and the probability of success (for both the AVTX-501 Milestone and the AVTX-007 Milestone and Royalties) are the largest drivers of the fair value, so changes to either would likely result in significant changes to their respective fair values.

In the event that J&J and/or Apollo are required to make payment(s) to ES Therapeutics pursuant to the underlying agreements, we will recognize revenue under our existing contracts with those customers for that amount when it is no longer probable there would be a significant revenue reversal with any differences between the fair value of the derivative liability related to that payment immediately prior to the revenue recognition and revenue recognized to be recorded as other expense. However, given we are no longer entitled to collect these payments, the potential ultimate settlement of the payments in the future from J&J and/or Apollo to ES Therapeutics (and the future mark-to-market activity each reporting period) will not impact our future cash flows.

Research and Development Costs

Research and development costs are expensed as incurred. These costs include, but are not limited to, expenses incurred under agreements with contract research organizations and investigative sites that conduct clinical trials and preclinical studies; the cost of acquiring, developing and manufacturing clinical trial materials; costs associated with preclinical activities and regulatory operations, pharmacovigilance and quality; costs and milestones associated with certain licensing agreements, and employee-related expenses, including salaries, benefits and stock-based compensation of research and development personnel.

Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to us by our vendors, such as clinical research organizations, with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development expense, as the case may be.

We are party to license and development agreements for in-licensed research and development assets with third parties. Such agreements often contain future payment obligations such as royalties and milestone payments. We recognize a liability (and related research and development expense) for each milestone if and when such milestone is probable and can be reasonably estimated. As typical in the biotechnology industry, each milestone has its own unique risks that we evaluate when determining the probability of achieving each milestone and the probability of success evolves over time as the programs progress and additional information is obtained. We consider numerous factors when evaluating whether a given milestone is probable including (but not limited to) the regulatory pathway, development plan, ability to dedicate sufficient funding to reach a given milestone and the probability of success.

Clinical Trial Expense Accruals

We estimate our expenses resulting from our obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. Our objective is to reflect the appropriate trial expenses in our financial statements by matching those expenses with the period in which services are performed and efforts are expended. We account for these expenses according to the progress of the trial as measured by subject progression and the timing of various aspects of the trial.

We determine accrual estimates by taking into account discussions with applicable personnel and outside service providers as to the progress or state of consummation of trials, or the services completed. During the course of a clinical trial, we adjust our clinical expense recognition if actual results differ from its estimates. We make estimates of our accrued expenses as of each balance sheet date based on the facts and circumstances known at that time. Our clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed might vary and might result in reporting amounts that are too high or too low for any particular period.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as defined by applicable SEC rules and regulations.

Recently Adopted Accounting Pronouncements

For a discussion of new accounting standards, see Note 2 to consolidated financial statements contained in this Annual Report on Form 10-K.

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

As a smaller reporting company, we are not required to provide the information required by this Item.

Item 8. Financial Statements and Supplementary Data.

The consolidated financial statements required to be filed pursuant to this Item 8 are appended to this report. An index of those consolidated financial statements is found in Item 15 of Part IV of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of the design and operation 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 report.

In designing and evaluating our disclosure controls and procedures, management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Based on their evaluation, our principal executive officer and principal financial officer concluded that as of December 31, 2025, our disclosure controls and procedures are designed to, and are effective to, provide assurance at a reasonable level that the information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosures as of December 31, 2025.

Management's Annual Report on Internal Control Over Financial Reporting

Our management, including our principal executive officer and principal financial officer, is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. Our internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2025, based on the Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework). Based on this evaluation under the 2013 Framework, our principal executive officer and principal financial officer have concluded that our internal control over financial reporting was effective at a reasonable level of assurance as of December 31, 2025.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the most recently completed fiscal quarter that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Attestation Report of Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to an exclusion for smaller reporting companies.

Item 9B. Other Information.

(b) Director and Officer Trading Plans and Arrangements

During the three months ended December 31, 2025, the following directors and officers had adopted contracts, instructions or written plans for the purchase or sale of our securities as follow:

Name and Title	Type of Trading Arrangement	Action Taken (Date of Action)	Duration or End Date	Aggregate Numbers of Securities to be Sold[(1)]	Description of Trading Arrangement
Mitchell Chan, Director	Trading plan intended to satisfy the affirmative defense conditions of Securities Exchange Act Rule 10b5-1(c)	Adoption (November 19, 2025)	November 30, 2026	42,833[(2)]	Exercises of vested stock options and sales of shares of the Company's common stock pursuant to terms of the trading plan
Mittie Doyle, Chief Medical Officer	Trading plan intended to satisfy the affirmative defense conditions of Securities Exchange Act Rule 10b5-1(c)	Adoption (November 13, 2025)	October 31, 2026	186,999	Exercises of vested stock options and sales of shares of the Company's common stock pursuant to terms of the trading plan
Jennifer Riley, Chief Strategy Officer	Trading plan intended to satisfy the affirmative defense conditions of Securities Exchange Act Rule 10b5-1(c)	Adoption (November 12, 2025)	November 30, 2026	12,000	Exercises of vested stock options and sales of shares of the Company's common stock pursuant to terms of the trading plan
Christopher Sullivan, Chief Financial Officer	Trading plan intended to satisfy the affirmative defense conditions of Securities Exchange Act Rule 10b5-1(c)	Adoption (November 12, 2025)	November 30, 2026	138,115[(3)]	Exercises of vested stock options and sales of shares of the Company's common stock pursuant to terms of the trading plan
Paul Varki, Chief Legal Officer	Trading plan intended to satisfy the affirmative defense conditions of Securities Exchange Act Rule 10b5-1(c)	Adoption (November 12, 2025)	June 30, 2026	92,771	Exercises of vested stock options and sales of shares of the Company's common stock pursuant to terms of the trading plan

(1) Represents the maximum number of shares that may be sold pursuant to the 10b5-1 arrangement. The number of shares sold is dependent on the satisfaction of certain conditions as set forth in the trading plans.

(2) These shares reflect the aggregate maximum of shares underlying vested stock options and RSUs, including 3,166 RSUs that are expected to vest during the term of the trading plan.

(3) These shares reflect the aggregate maximum of shares underlying vested stock options and RSUs, including 24,200 RSUs that are expected to vest during the term of the trading plan prior to expected share withholding or sell-to-cover to satisfy tax withholding obligations associated with the expected RSU vest.

Other than as disclosed above, none of our directors or officers adopted, modified or terminated any Rule 10b5-1(c) trading arrangements or any non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K) during the three months ended December 31, 2025.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

BOARD OF DIRECTORS

The Board currently consists of nine members, each of which serve for a one-year term or until a successor has been elected and qualified. Vacancies on the Board may be filled only by persons elected by a majority of the remaining directors in office. A director elected by the Board to fill a vacancy, including vacancies created by an increase in the number of directors, shall serve for the remainder of the year term and until the director's successor is duly elected and qualified.

The following table sets forth information of the members of our Board:

Name	Age	Director Since	Position(s) with Avalo
Michael Heffernan	61	March 2025	Chairman of the Board of Directors
Garry Neil, M.D.	72	June 2022	Chief Executive Officer and Director
Mitchell Chan	45	December 2021	Director
Jonathan Goldman, M.D.	61	March 2024	Director
Rita Jain, M.D.	63	June 2025	Director
Aaron Kantoff	40	March 2024	Director
Gilla Kaplan, Ph.D.	78	October 2020	Director
Kevin Lind	49	October 2025	Director
Samantha Truex	55	March 2024	Director

The following is a brief biography of each current director:

Michael Heffernan. Mr. Heffernan has served as the Chairman of the Board since March 2025. Mr. Heffernan is a seasoned biopharmaceutical executive and entrepreneur with over 30 years of experience in the industry. He is the Founder and has served as Chairman Emeritus of Collegium Pharmaceutical, Inc. ("Collegium") (Nasdaq: COLL) since May 2025, and has previously served in multiple roles at Collegium, including as its President and Chief Executive Officer between October 2003 to July 2018, as Interim CEO between May 2024 to November 2024, and as Chairman between October 2003 to May 2025. Mr. Heffernan previously was Chairman and Chief Executive Officer at Onset Dermatologics, Inc., a commercial stage dermatology company that he founded and spun out of Collegium to create PreCision Dermatology, Inc. (acquired by Valeant), as well as the co-founder and Chief Executive Officer of Clinical Studies Ltd., a pharmaceutical contract research organization (acquired by PhyMatrix Corp.). Mr. Heffernan began his career at Eli Lilly and Company where he served in numerous sales and marketing roles. Currently, Mr. Heffernan serves as board member of several privately-held companies, including K36 Therapeutics, Inc., since November 2022, as well as Chairman of the board of directors at several privately-held companies, including NMD Pharma A/S since December 2022, Par Health, Inc., since November 2025 and AAVantgarde Bio, Inc., since October 2023. Mr. Heffernan is a board member of Biohaven (NYSE: BHVN) since September 2022, Trevi Therapeutics, Inc. (Nasdaq: TRVI) since May 2017, EnGene Holdings,, Inc. (Nasdaq: ENGN), since July 2025 and previously served as a member of the board of directors at Synlogic, Inc. (Nasdaq: SYBX) between December 2020 to February 2025. He holds a Bachelor of Science in Pharmacy from the University of Connecticut and is a registered pharmacist. Our Board believes that Mr. Heffernan's extensive experience in building and leading biopharmaceutical companies, executing successful exits, and driving shareholder value makes him a valuable member of our Board.

Garry Neil, M.D. Dr. Neil has served as the President and Chief Executive Officer of the Company since February 2022 and has served on our Board since June 2022. Dr. Neil previously served as Chairman of our Board from August 2022 until March 2025 and from March 2020 to February 2022, Dr. Neil served as our Chief Scientific Officer. Dr. Neil joined the Company as Chief Medical Officer in February 2020, when Aevi Genomic Medicine, Inc. ("Aevi") was acquired by the Company (the "Aevi Merger"). Dr. Neil served as Chief Scientific Officer of Aevi from September 2013 until the Aevi Merger closed in February 2020. From September 2012 to September 2013, Dr. Neil was a Partner at Apple Tree Partners, a life sciences private equity fund. From July 2002 to August 2012, he held a number of senior positions at Johnson & Johnson, including Corporate VP of Science & Technology from November 2007 to August 2012, and Group President at Johnson & Johnson Pharmaceutical Research and Development from September 2005 to November 2007.

Prior to joining Johnson & Johnson, he held senior positions at AstraZeneca, EMD Pharmaceuticals Inc. and Merck KGaA. Under his leadership, a number of important new medicines for the treatment of cancer, anemia, infections, central nervous system and psychiatric disorders, pain, and genitourinary and gastrointestinal diseases gained initial or expanded approvals. Since June 2022, Dr. Neil has served on the board of Celldex Therapeutics, Inc. (Nasdaq: CLDX). Previously, Dr. Neil served on the board of directors of Arena Pharmaceuticals, Inc. (previously, Nasdaq: ARNA) from March 2017 until it was acquired by Pfizer Inc. (NYSE: PFE) in March 2022, of Zura Bio Ltd. (Nasdaq: ZURA) between January 2023 to November 2023 and GTx, Inc. (previously Nasdaq: GTXI) between August 2016 to May 2019. Dr. Neil also served on the Board of Directors of the Reagan Udall Foundation and the Center for Discovery and Innovation between 2007 to 2021 and was also the past founding chairman and board member of TransCelerate Biopharma, Inc., between 2012 to 2019. He is a past Chairman of the Pharmaceutical Research and Manufacturers Association ("PhRMA") Science and Regulatory Executive Committee and the PhRMA Foundation Board, as well as a past member of the Foundation for the U.S. National Institutes of Health ("NIH") and the Science Management Review Board of the NIH. Dr. Neil holds a B.S. from the University of Saskatchewan and an M.D. from the University of Saskatchewan College of Medicine. He completed postdoctoral clinical training in internal medicine and gastroenterology at the University of Toronto. Dr. Neil also completed a postdoctoral research fellowship at the Research Institute of Scripps Clinic. Our Board believes that Dr. Neil's wealth of scientific and medical training combined with his substantial leadership skills and board experience makes him a valuable member of our Board.

Mitchell Chan. Mr. Chan has served on our Board since December of 2021. Mr. Chan has served as the Chief Financial Officer of REGENXBIO (Nasdaq: RGNX) since September 2024. Mr. Chan previously served as the Chief Financial Officer and Chief Business Officer at ABio-X Holdings, Inc., a healthcare-dedicated incubator, from May 2023 to October 2023. From January 2022 to April 2023, Mr. Chan served as an Operating Partner at Catalio Capital Management, LP, a venture capital fund focused on investments in biomedical technology companies. From September 2018 to June 2022, Mr. Chan was at Viela Bio, Inc. (previously, Nasdaq: VIE), a clinical-stage biotechnology company, and in his last role served as the Chief Financial Officer and oversaw the acquisition of Viela by Horizon Therapeutics plc. Prior to Viela, Mr. Chan served as the Director of Investor Relations for AstraZeneca, North America (Nasdaq: AZN), a multinational pharmaceutical and biotechnology company. Mr. Chan also held several roles of increasing responsibility within the Roche Group, at Genetech, Inc. and F. Hoffmann-La Roche AG, including in biooncology commercial finance, research and development finance, and mergers and acquisitions. Mr. Chan is the recipient of Executive Certifications from Stanford University, University of California (Haas), and University of Pennsylvania (Wharton) and earned his B.S. in Biochemistry, M.S. in Medial Biophysics, and MBA from the University of Toronto (Rotman School of Management). Our Board believes that Mr. Chan's years of leadership experience in the finance and investor relation functions at successful life science companies makes him a valuable member of our Board.

Jonathan Goldman, M.D. Dr. Goldman has served on our Board since March 2024. Dr. Goldman has 30 years of experience across life sciences as a Chief Executive Officer, Chief Medical Officer, investor, and senior executive. Since February 2023, he currently serves as the CEO of Clinical Ink, Inc., a global life science company that brings data, technology, and patient-centric research together. Prior to Clinical ink, Dr. Goldman served as the CEO, between October 2018 to December 2022, and as a board member, between December 2018 to March 2023, of Abzena Limited. Dr. Goldman was also the operating partner at Welsh, Carson, Anderson & Stowe between August 2017 to February 2023 and was previously the CEO of Aptuit LLC. He has also held senior executive positions at ICON PLC (Nasdaq: ICON) and Point Biomedical Corp., in addition to holding appointments as Associate Clinical Professor of Medicine in the division of Cardiology at the University of California San Francisco, and as an Attending Cardiologist at the San Francisco Veterans Administration Medical Center. Dr. Goldman trained in medicine at St. Bartholomew's Hospital Medical College, in London and in Cardiology at St. George's Hospital, London. He received B.Sc., M.B.B.S and M.D. degrees from the University of London, UK. He was awarded MBAs by Columbia University in New York and the University of California at Berkeley. Our Board believes that Dr. Goldman's experience across life sciences in manufacturing, commercial and operations makes him a valuable member of our Board.

Rita Jain, M.D. Dr. Jain has served on our Board since June 2025. Dr. Jain is a Rheumatologist who brings over two decades of leadership experience in biopharmaceutical development, clinical strategy, and regulatory affairs across multiple therapeutic areas, including immunology, inflammation, nephrology, and rare diseases. She most recently served on the board of directors (between 2019 to 2022) and as Executive Vice President and Chief Medical Officer (from 2021) at ChemoCentryx, Inc. (previously, Nasdaq: CCXI), where she advanced development and supported commercialization of Tavneos® (avacopan), a first-in-class treatment for ANCA-associated vasculitis, and supported the company's acquisition by Amgen in 2022. Prior to that, she was Senior Vice President and Chief Medical Officer at Akebia Therapeutics, Inc. (Nasdaq: AKBA) from 2017 to 2019. Additionally, Dr. Jain held key leadership positions at Abbott Laboratories, Inc. (NYSE: ABT) between 2003 to 2012, AbbVie, Inc. (Nasdaq: ABBV) between 2013 to 2016, Pfizer, Inc. (NYSE: PFE), Heartwood Biopharma Group between 2021 to 2023 and Immunovant, Inc. (Nasdaq: IMVT) in 2021, overseeing global development programs, regulatory interactions, and clinical operations for multiple therapeutic candidates. Currently, she serves on the boards of Celldex Therapeutics, Inc. (Nasdaq: CLDX) since February 2023, AnaptysBio, Inc. (Nasdaq: ANAB) since April 2023 and SAB Biotherapeutics, Inc. (Nasdaq: SABS) since January 2026. Dr. Jain previously served as an advisory board member at AM-Pharma B.V. between 2020 to 2023 and at Prevention Bio, Inc., from January 2023 until its acquisition by Sanofi in April 2023.

Dr. Jain received her M.D. from the State University of New York at Stony Brook School of Medicine and completed her residency in internal medicine at Staten Island University Hospital, followed by a fellowship in rheumatology at North Shore University Hospital and a Clinical Research Fellowship at the University of Texas Southwestern Medical Center, Dallas. Our Board believes that Dr. Jain's extensive experience spanning clinical development, regulatory strategy, and executive leadership at multiple development-stage biopharma companies make her a valuable member of our Board.

Aaron Kantoff. Mr. Kantoff has served on our Board since March 2024. Since January 2022, Mr. Kantoff is co-founder and managing partner of Scion Life Sciences Management, LLC, which is affiliated with Petrichor Healthcare Capital Management LP. Most recently, between April 2022 to November 2025, he has served on the board of directors of Tourmaline Bio, Inc. (Nasdaq: TRML), a biotechnology company focused on autoimmune diseases. Mr. Kantoff was a co-founder and board director of RayzeBio, Inc. (Nasdaq: RYZB) from April 2020 until January 2024. Previously, he was a venture partner at Medicxi Ventures (UK) LLP ("Medicxi"), an investment firm focused on the life sciences sector. During his time as venture partner at Medicxi, he served on the board of directors of Centessa Pharmaceuticals plc (Nasdaq: CNTA) from November 2020 to July 2022. From August 2011 until April 2019, Mr. Kantoff served as a partner at Apple Tree Partners ("ATP"), a biotechnology venture capital firm. During his time at ATP, Mr. Kantoff was a board member of Syntimmune, Inc. (acquired by Alexion Pharmaceuticals, Inc. (formerly Nasdaq: PALXN), which was subsequently subject to a tender offer by a third party), Corvidia Therapeutics, Inc. (acquired by Novo Nordisk A/S (NYSE: NVO)), Akero Therapeutics, Inc. (previously Nasdaq: AKRO), as well as other privately-held and publicly traded biotechnology companies. Prior to joining ATP, Mr. Kantoff held roles in private equity and investment banking. Mr. Kantoff received a B.S. in finance and international business from the New York University Leonard N. Stern School of Business. Our Board believes that Mr. Kantoff's prior board experience and his extensive experience in the venture capital and life sciences industries makes him a valuable member of our Board.

Gilla Kaplan, Ph.D. Dr. Kaplan has served on our Board since October 2020. She has spent her career as an academic research scientist leading her laboratory in investigations focusing on human disease, and exploring novel experimental medicine approaches that modulate the immune response for disease control. Dr. Kaplan's work has encompassed developing a deep understanding of the cellular immune response and how to harness it for host adjunctive therapies. She is the co-founder and served as the Chief Research Officer of Gilrose Pharmaceuticals, Inc. Previously, from July 2018 until December 2020, Dr. Kaplan was Senior Advisor at the Bill and Melinda Gates Medical Research Institute and was the Director of the Global Health Program, Tuberculosis, at the Bill and Melinda Gates Foundation ("BMGF") from January 2014 until April 2018. Building on her 20-year research experience at Rockefeller University in New York City and then 10-year research experience at the Public Health Research Institute Center at the University of Medicine and Dentistry of New Jersey, she led the reshaping of the tuberculosis program at BMGF. Dr. Kaplan is the recipient of multiple grants from the U.S. National Institutes of Health-National Institute of Allergy and Infectious Diseases and other funding organizations for her research. Dr. Kaplan currently serves as a member of the board of directors of Tyra Biosciences, Inc. (Nasdaq: TYRA) and previously served as a member of the board of directors of Celgene Corporation (previously Nasdaq: CELG). Dr. Kaplan received her B.Sc. in Microbiology and Physiology from the Hebrew University, Jerusalem, Israel and her M.Sc. and her Ph.D. in Cellular Immunology from the University of Tromso, Norway. Our Board believes that Dr. Kaplan's academic and industry experience in immunology makes her a valuable member of Board.

Kevin Lind. Mr. Lind has served on our Board since October 2025. Mr. Lind recently served as the President and Chief Executive Officer Longboard Pharmaceuticals, Inc. (previously Nasdaq: LBPH) and as a member of Longboard's board of director from between February 2020 until December 2024 when Longboard was acquired by H. Lundbeck A/S. Prior to co-founding Longboard Pharmaceuticals, Mr. Lind served as EVP and Chief Financial Officer during the turnaround of Arena Pharmaceuticals, Inc. (previously Nasdaq: ARNA), which was later acquired by Pfizer in 2022, from 2016 to 2020. During his tenure as an executive leader at these organizations, he successfully raised over $1.1 billion in equity capital, secured valuable business development partnerships, spun out two organizations, and was instrumental in activities resulting in the successful acquisitions of both companies. At Longboard, Mr. Lind also led the innovative drug development strategies resulting in the conceptualization of a novel medical indication and securing of Breakthrough Therapy designation from the U.S. FDA for a Phase 3 neurological drug candidate for developmental and epileptic encephalopathies. Prior to Arena, Mr. Lind focused on healthcare investing at TPG Special Situations Partners from 2009 to 2016 and at TPG-Axon from 2006 to 2008. He served in various capacities as a healthcare investment banker at Lehman Brothers, Inc., a former global financial services firm, from 1998 to 2002 and 2004 to 2006. Currently, Mr. Lind serves as board member of several privately-held companies, including Apnimed, Inc., since March 2025 and Cavalry Biosciences, Inc., since September 2025 and has previously served as a member of the board of directors at Ceek Women's Health between November 2021 to January 2024. Mr. Lind received a B.S. from Stanford University in Biological Sciences and an MBA from UCLA Anderson School of Management. Our Board believes that Mr. Lind's leadership experience notably in financial and corporate strategy and business development execution makes him a valuable member of our Board.

Samantha Truex. Ms. Truex has served on our Board since March 2024. Ms. Truex is a seasoned biotech executive with almost 30 years of industry experience. Since May 2025, she has served as Chief Executive Officer of Oblenio Bio, Inc., a portfolio company launched by Aditum. Previously, Ms. Truex was the founding chief Executive Officer of Upstream Bio, Inc., from October 2021 to March 2024, and the Chief Executive Officer of Quench Bio, Inc. from August 2018 to March 2021.

Ms. Truex served as the Chief Operating Officer and Head of Corporate Development at Synlogic Therapeutics, Inc. from December 2016 to June 2017, where she led the company through a reverse merger with Mirna Therapeutics, Inc. and served as Chief Business Officer of Padlock Therapeutics, Inc. from September 2014 to June 2016, where she led the sale of the company to Bristol Myers Squibb. Previously, Ms. Truex was Vice President of Corporate Development at Biogen Inc. (Nasdaq: BIIB) where she led transactional business development activities and served as program executive for now-marketed products FAMPYRA®, ELOCTATE™ and ALPROLIX™. Ms. Truex also previously worked in Corporate Development at Genzyme, Chiron Diagnostics and in consulting for Health Advances. She was also an Entrepreneur in Residence at Atlas Venture from October 2014 to August 2021. Since June 2022, Ms. Truex has served on the board of Artios Pharma Limited, privately-held life sciences company, and has previously served on the boards of Hotspot Therapeutics, Inc. from 2018 to 2022, iPierian, Inc. from 2012 until its acquisition by Bristol Myers Squibb in 2014 and True North Therapeutics from 2012 to 2014. Ms. Truex earned a B.A. in biology from Dartmouth College, a B.E. in biomedical engineering from the Thayer School at Dartmouth and an MBA from the Tuck School at Dartmouth. Ms. Truex is the chair emeritus of the Board of Advisors for Thayer School of Engineering at Dartmouth and is a member of the Board of Advisors for Life Science Cares. Our Board believes that Ms. Truex's experience leading successful life science companies, as well as her experience in business and corporate development, makes her a valuable member of our Board.

EXECUTIVE OFFICERS

The following table sets forth information of our executive officers:

Name	Age	Position(s) with Avalo
Garry Neil, M.D.	72	Chief Executive Officer
Taylor Boyd	37	Chief Business Officer
Mittie Doyle, M.D., FACR	61	Chief Medical Officer
Jennifer Riley	51	Chief Strategy Officer
Christopher Sullivan	42	Chief Financial Officer
Paul Varki	53	Chief Legal Officer

The following is a brief biography of each current executive officer:

Garry Neil, M.D. The biography for Dr. Neil is located in "Board of Directors" above.

Taylor Boyd. Mr. Boyd has served as Avalo's Chief Business Officer since October 2025. Mr. Boyd has nearly 15 years of experience across biotech business development, corporate finance, and investment banking. Most recently, he served as Executive Vice President & Chief Business Officer at Abzena Limited ("Abzena") between February 2025 to October 2025, where he led strategic mergers and acquisitions, licensing, and portfolio expansion initiatives. Prior to Abzena, he was Vice President and Head of Business Development at Longboard Pharmaceuticals, Inc. ("Longboard") between January 2024 to January 2025, where he led activities that ultimately culminated with its acquisition by Lundbeck. Prior to Longboard, he held leadership roles at Oxford Biomedica US, Inc., and investment banking roles at Raymond James, SVB Leerink, Cantor Fitzgerald, and RBC Capital Markets where he executed more than $40 billion in mergers and acquisitions and debt and equity capital markets transactions. Mr. Boyd earned his B.S. in Accountancy with a concentration in Managerial Accounting from North Carolina State University and his M.S. in Accountancy with a concentration in Transaction Advisory Services from Wake Forest University's Babcock Graduate School of Management.

Mittie Doyle, M.D., FACR. Dr. Doyle has served as Avalo's Chief Medical Officer since July 2024. She most recently served as Chief Medical Officer at Aro Biotherapeutics, Co., a biotechnology company specializing in tissue-targeted genetic medicines, from September 2021 to July 2024. Prior to that, she served as Vice President, Global Therapeutic Area Head, Immunology at CSL Behring, a global biotech company, from October 2017 to October 2021. Prior to her time at CSL Behring, Dr. Doyle held senior level roles as Vice President, Global Development Lead at Shire Pharmaceuticals, plc between August 2016 to October 2017, Vice President, Clinical Research, Flexion Therapeutics, Inc., between April 2015 to August 2016 and Senior Medical Director at Alexion Pharmaceuticals, Inc. (previously, Nasdaq: ALXN) between June 2012 to April 2021. Dr. Doyle currently serves on the Board of Directors of Santa Ana Bio, Inc., a precision immunology company developing targeted therapies for patients with autoimmune and inflammatory diseases. Previously, Dr. Doyle served on the board of directors of DICE Therapeutics, Inc. ("DICE"), a former public company, from March 2022 until DICE was acquired by Eli Lilly and Company in August 2023. During her career, Dr. Doyle has advanced assets across a broad range of immune-mediated and orphan diseases and has led teams with responsibilities for design and execution of first-in-human through Phase 2 and 3 trials, resulting in several global regulatory approvals. Dr. Doyle received her B.A. magna cum laude from Princeton University in Romance Languages and her M.D. cum laude from Yale Medical School.

She completed her postdoctoral training at Harvard Medical School including residency in Internal Medicine at Massachusetts General Hospital and clinical/research fellowship in Rheumatology and Immunology at Brigham and Women's Hospital.

Jennifer Riley. Ms. Riley has served as Avalo's Chief Strategy Officer since January 2025. In October 2014, she founded Northbrook Consulting, LLC, where she provided operational support related to development strategies, commercialization, and portfolio optimization to numerous companies in the biopharmaceutical industry until December 2024. Prior to that, she served in numerous senior leadership roles at Biogen Inc. (Nasdaq: BIIB), from 2005 to 2012, most recently serving as Vice President of Program Leadership and Management, overseeing the strategy and launch readiness for its hemophilia franchise. She also served in the role of Country Manager, where she led sales and marketing for two leading multiple sclerosis products from 2009 to 2010. Ms. Riley's prior roles with Biogen include Vice President – Global Cardiopulmonary Marketing, from 2007 to 2009, where she built the team and established the organizational model for the new business area, and Director of Operations, in 2007, where she oversaw the integration activities following the acquisition of Syntonix Pharmaceutics, Inc. by Biogen. Prior to Biogen, Ms. Riley served at Health Advances, LLC from 2000 to 2004, where she led strategic product, portfolio, and corporate planning initiatives for client organizations in the biopharmaceutical, medical device, and diagnostics markets. From 1996 to 1999, Ms. Riley was a graduate student at Harvard Medical School's Department of Microbiology and Molecular Genetics, where she conducted research in the field of host immune response to viral infection and mechanisms of viral immune evasion. Ms. Riley received her B.S. magna cum laude from the University of California, San Diego in molecular biology and her M.A. in virology from Harvard University, where she also completed professional education at the Harvard Business School.

Christopher Sullivan. Mr. Sullivan has served as Avalo's Chief Financial Officer since February 2022. Prior to his appointment as Chief Financial Officer, Mr. Sullivan served as Chief Accounting Officer of the Company between March 2021 to February 2022. From April 2020 to February 2021, Mr. Sullivan served as the Company's Interim Chief Financial Officer, principal financial officer, and principal accounting officer. Previously, Mr. Sullivan was the Vice President of Finance at the Company and served various other escalating roles since joining the Company in April 2018. Mr. Sullivan brings a strong public company and life science background, including significant experience with equity and debt capital raises, acquisitions, divestitures, in and out-license transactions, enterprise resource planning implementations, and financial planning and analysis from leading finance and accounting functions at various public biotechnology, molecular diagnostic, and pharmaceutical companies. Prior to joining the Company, Mr. Sullivan was the Corporate Controller for Sucampo Pharmaceuticals, Inc., a previously Nasdaq listed global biopharmaceutical company, from August 2017 to April 2018, until it was acquired by Mallinckrodt plc. From November 2015 to August 2017, Mr. Sullivan was the Corporate Controller for OpGen Inc. (Nasdaq: OPGN), a microbial genetics analysis company, and prior to that was a Senior Manager at Ernst & Young, LLP where he was employed from August 2005 to October 2015. Mr. Sullivan received his B.S. degrees in and Finance and Accounting from the University of Maryland, College Park, where he graduated magna cum laude and is a Certified Public Accountant.

Paul Varki. Mr. Varki has served as Avalo's Chief Legal Officer since June 2024. Mr. Varki brings over 20 years of experience providing counsel in the pharmaceutical industry. He most recently served as General Counsel, Vice President, Head of Legal U.S., at Idorsia Pharmaceuticals US Inc., a biopharmaceutical company specializing the development of small molecules, from July 2020 to June 2024. Prior to that, from November 2018 to July 2020, he served as Vice President, Legal, at Amarin Corporation plc, a pharmaceutical cardiovascular care company. He led the legal and compliance functions as Senior Vice President, General Counsel, Chief Compliance Officer and Corporate Secretary at Braeburn Pharmaceuticals, Inc. between September 2017 to November 2018 and at Egalet Corporation between November 2015 to August 2017. Prior to that from January 2004 to November 2015, he held various legal roles of increasing responsibility at GlaxoSmithKline, including Counsel – US Pharmaceuticals, Senior Counsel – Global Vaccines and Biologics, and Assistant General Counsel – Global Research and Development. Earlier in his career, Mr. Varki practiced as FDA regulatory law at Reed Smith LLP between December 2002 to January 2004 and has served as Regulatory Counsel at the Center for Drug Evaluation and Research at the FDA between September 2000 to December 2002. Mr. Varki has a J.D. from Temple University School of Law, a Master of Public Health from George Washington University, and a Bachelor of Arts from the College of William and Mary.

CODE OF ETHICS

The Company has adopted the Avalo Therapeutics, Inc. Code of Business Conduct and Ethics that applies to all officers, directors and employees (the "Code of Ethics"). The Code of Ethics is available under the heading "Corporate Governance" on the Company's website at *ir.avalotx.com*. If the Company makes any substantive amendments to the Code of Ethics or grants any waiver from a provision of the Code of Ethics to any executive officer or director, the Company will promptly disclose the nature of the amendment or waiver on its website.

CORPORATE GOVERNANCE GUIDELINES

In June 2015, the Board documented the governance practices followed by the Company by adopting Corporate Governance Guidelines (the "Guidelines") to assure that the Board will have the necessary authority and practices in place to review and evaluate the Company's business operations as needed and to make decisions that are independent of the Company's management. The Guidelines were amended by the Board in August 2019.

The Guidelines are also intended to align the interests of directors and management with those of the Company's stockholders. The Guidelines set forth the practices the Board intends to follow with respect to Board composition and selection, the role of the Board, director orientation and education, Board meetings and involvement of senior management, Chief Executive Officer performance evaluation and succession planning and Board committees and compensation. The Guidelines, as well as the charters for each committee of the Board, may be viewed under the heading "Corporate Governance" at *ir.avalotx.com*.

Insider Trading Policy

Additionally, the Company has adopted an insider trading policy (the "Insider Trading Policy") governing the purchase, sale, and other dispositions of Company securities by its directors, officers, employees, and the Company itself. The Insider Trading Policy also strongly discourages employees, consultants, officers and directors from engaging in short sales, transactions in put or call options, hedging transactions, margin accounts or other inherently speculative transactions with respect to the Company's stock at any time. The Insider Trading Policy is reasonably designed to promote compliance with insider trading laws, rules, and regulations. A copy of our Insider Trading Policy is filed as Exhibit 19.1 of this Annual Report on Form 10-K.

Audit Committee and Audit Committee Financial Expert

The Audit Committee assists the Board in its oversight of the integrity of the Company's financial statements, the qualifications and independence of our independent auditors, and our internal financial and accounting controls. The Audit Committee has direct responsibility for the appointment, compensation, retention (including termination) and oversight of our independent auditors, and our independent auditors report directly to the Audit Committee. The Audit Committee also prepares the audit committee report that the SEC requires to be included in our annual proxy statement.

The Audit Committee is currently composed of three directors: Mr. Lind (chair), Mr. Chan, and Dr. Jain. Mr. Lind joined the Audit Committee effective October 1, 2025 and was appointed as chair of the Audit Committee, effective January 1, 2026. Dr. Jain was appointed as a member of the Audit Committee effective January 1, 2026.

The Board reviews the Nasdaq Listing Rules definition of independence for Audit Committee members annually and has determined that all members of the Audit Committee are independent as defined in Rule 5605(c)(2)(A)(i) of the Nasdaq Listing Rules. The Board has also determined that Mr. Lind qualifies as an "audit committee financial expert," as defined in applicable SEC rules. The Board made qualitative assessments of Mr. Lind's level of knowledge and experience based on a number of factors, including formal education and experience. Previously, Mr. Chan served as the chair of the Audit Committee in 2025 and during such time, the Board had determined that Mr. Chan qualified as an "audit committee financial expert," as defined in applicable SEC rules.

The Audit Committee met four times during 2025. The Board has adopted a written Audit Committee charter that is available to stockholders under the heading "Corporate Governance" on the Company's website at *ir.avalotx.com*.

Compensation Committee

The Compensation Committee approves the compensation objectives for the Company, approves the compensation of the principal executive officer and approves or recommends to our Board for approval the compensation of other executives. The Compensation Committee reviews all compensation components, including base salary, bonus, benefits and other perquisites.

The Compensation Committee is currently composed of three directors: Mr. Kantoff (chair), Ms. Truex and Mr. Lind. Mr. Lind was appointed as a member of the Compensation Committee effective January 1, 2026.

The Board reviews the independence for Compensation Committee members annually and has determined that all members of the Compensation Committee, during their respective periods of service on the Compensation Committee, are independent as defined in Rule 5605(d)(2) of the Nasdaq Listing Rules and each is a non-employee member of our Board as defined in Rule 16b-3 under the Exchange Act.

The Compensation Committee met four times during 2025. The Board has adopted a written Compensation Committee charter that is available to stockholders under the heading "Corporate Governance" on the Company's website at *ir.avalotx.com*.

Nominating and Corporate Governance Committee

The Nominating and Corporate Governance Committee of the Board is responsible for making recommendations to our Board regarding candidates for directorships and the structure and composition of our Board and the Board committees. In addition, the Nominating and Corporate Governance Committee is responsible for maintaining and recommending to our Board corporate governance guidelines applicable to the Company and advising our Board on corporate governance matters.

The Nominating and Corporate Governance Committee is currently composed of three directors: Ms. Truex (Chair), Mr. Kantoff and Dr. Kaplan. The Board reviews the independence for the Nominating and Corporate Governance Committee members on an annual basis and has determined that all members of the Nominating and Corporate Governance Committee, during their respective periods of service on the Nominating and Corporate Governance Committee, are independent as defined in Rule 5605(a)(2) of the Nasdaq Listing Rules.

The Nominating and Corporate Governance Committee met six times during 2025. The Board has adopted a written Nominating and Corporate Governance Committee charter that is available under the heading "Corporate Governance" on the Company's website at *ir.avalotx.com*.

SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Exchange Act requires the Company's directors and executive officers, and persons who own more than ten percent of a registered class of the Company's equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of common stock and other equity securities of the Company. Officers, directors and greater than ten percent stockholders are required by SEC regulation to furnish the Company with copies of all Section 16(a) forms they file.

To the Company's knowledge, based solely on the review of the copies of such reports filed with the SEC and/or furnished to the Company and written representations from the Company's directors and executive officers that no other reports were required, during the year ended December 31, 2025, all officers, directors and greater than ten percent beneficial owners were in compliance with applicable Section 16(a) filing requirements.

Item 11. Executive Compensation.

The following table shows for the fiscal years ended December 31, 2025 and 2024, compensation awarded to or paid to, or earned by, anyone serving as principal executive officer during the most recently completed fiscal year and our next two most highly compensated executive officers who served as an executive officer during the year ended December 31, 2025 (the "Named Executive Officers").

Name and Principal Position	Year	Salary	Non-Equity Incentive Plan Compensation [1]	Option Awards[2]	Stock Awards[2]	All Other Compensation [4]	Total
Garry Neil, M.D. *Chief Executive Officer, President, Chairman of the Board and principal executive officer*	2025	$590,000	$474,950	$2,732,298	$— [3]	$10,333	$3,807,581
	2024	$532,500	$501,800	$4,255,801	$1,922,648	$—	$7,212,749
Taylor Boyd *Chief Business Officer [5]*	2025	$116,250	$52,080	$3,049,481	$—	$1,940	$3,219,751
	2024	$—	$—	$—	$—	$—	$—
Mittie Doyle, M.D., FACR *Chief Medical Officer*	2025	$512,500	$229,600	$1,030,429	$— [3]	$8,028	$1,780,557
	2024	$231,061	$216,000	$2,586,696	$—	$—	$3,033,757

(1) The amounts reflect the annual bonus earned for the given fiscal year based on the achievement of goals as recommended by the Compensation Committee and approved by the Board. The annual bonus is typically paid in the year following the year it was earned. The 2024 amounts also include a retention bonus paid to Dr. Neil in 2024.

(2) The amounts reflect the grant date fair value for option awards and performance stock unit awards (if applicable), respectively, granted during 2025 and option awards and restricted stock unit awards, respectively, granted during 2024 in accordance with FASB Topic ASC 718, *Compensation–Stock Compensation*, excluding the estimate of forfeitures. The assumptions used in valuing these options and restricted stock unit awards are described in Note 12 to our consolidated financial statements for the year ended December 31, 2025. For option awards, compensation will only be realized to the extent the market price of our common stock is greater than the exercise price of such option award. For performance stock unit awards, compensation will only be realized to the extent that the performance metrics are met and will depend on the actual outcome of the performance conditions.

(3) Amounts represent the aggregate grant date fair value for grants of performance stock units ("PSUs") made to Dr. Neil and Dr. Doyle in 2025, calculated in accordance with the provisions of FASB ASC Topic 718, *Compensation–Stock Compensation*. In accordance with SEC rules, these amounts are calculated based on the probable outcome of the performance conditions as of the grant date. The grant date fair value of the PSUs was $0 as the Company did not consider the achievement of the performance metrics to be probable in accordance with ASB Topic ASC 718, *Compensation–Stock Compensation.* Assuming the highest level of performance is achieved, the grant date fair value of such PSUs would be $2.2 million for Dr. Neil and $1.0 million for Dr. Doyle.

(4) The amounts reported in this column represent 401(k) matching contributions.

(5) Mr. Boyd joined us in October 2025. Accordingly, the amount reported in the "Salary" column reflects his partial year of employment, and the amount reported in Non-Equity Incentive Plan Compensation column has been prorated to reflect his partial year of employment.

Narrative to Summary Compensation Table

We review compensation annually for all employees, including our Named Executive Officers. In setting annual base salaries and bonuses and granting equity incentive awards, we consider (i) compensation for comparable positions in the market, (ii) individual performance as compared to our expectations and objectives, (iii) our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders, and (iv) a long-term commitment to our Company.

Our Board historically has determined our executives' compensation based on the recommendations of our Compensation Committee, which typically reviews and discusses management's proposed compensation with the Chief Executive Officer for all executives other than the Chief Executive Officer. Based on those discussions and its discretion, the Compensation Committee then recommends the compensation for each executive officer to the Board. Our Board, without members of management present, discusses the Compensation Committee's recommendations and ultimately approves the compensation of our executive officers.

Annual Base Salary

We have entered into employment agreements with each of our Named Executive Officers that establish annual base salaries, which are generally determined, approved and reviewed periodically by our Compensation Committee in order to compensate our Named Executive Officers for the satisfactory performance of our duties to our Company. Annual base salaries are intended to provide a fixed component of compensation to our Named Executive Officers, reflecting their skill sets, experience, roles and responsibilities. Base salaries for our Named Executive Officers have generally been set at levels deemed necessary to attract and retain individuals with superior talent. The following table presents the annual base salaries for each of our Named Executive Officers for 2025, as determined by the Compensation Committee.

Name	2025 Annualized Base Salary
Garry Neil, M.D.	$590,000
Taylor Boyd	$465,000
Mittie Doyle, M.D., FACR	$512,500

Annual Bonus

Our bonus plan motivates and rewards our Named Executive Officers for achievements relative to our goals and expectations for each fiscal year. Our Named Executive Officers are eligible to receive annual bonuses calculated as a target percentage of their annual base salaries, based on our Compensation Committee and Board's assessment of their individual performance and our Company's results of operations and financial condition. The target annual bonus for Dr. Neil, Mr. Boyd, and Dr. Doyle were 70%, 40% and 40% of their respective base salaries.

As recommended by the Compensation Committee and approved by the Board, our Named Executive Officers received a bonus relative to achievement of goals for fiscal year 2025. In accordance with his employment agreement, the annual bonus for Mr. Boyd related to fiscal year 2025, his first year of employment, was prorated based on his start date.

Equity-Based Awards

Our equity-based incentive awards are designed to align our interests with those of our employees and consultants, including our Named Executive Officers. Our Compensation Committee is generally responsible for approving equity grants. Vesting of equity awards is generally tied to continuous service with the Company and serves as an additional retention measure. Our executives are typically awarded an initial grant upon commencement of employment and an annual grant each year. Additional grants may occur periodically in order to specifically incentivize executives.

In April 2016, the Board adopted the 2016 Equity Incentive Plan, which was approved by our stockholders in May 2016 and which was subsequently amended and restated in May 2018 and in August 2019 with the approval of our Board and stockholders. In June 2024, the Board approved a fourth amended and restated equity incentive plan, which was subsequently approved by the Company's stockholders in August 2024 (the "2016 Fourth Amended Plan").

The purpose of the 2016 Fourth Amended Plan is to attract and retain employees, non-employee directors and consultants, and advisors. Our 2016 Fourth Amended Plan authorizes us to make grants to eligible recipients of non-qualified stock options, incentive stock options, restricted stock awards, restricted stock units and stock-based awards.

Other Compensation

Our named executive officers are eligible to participate, on the same basis as our other employees, in our employee benefit plans, including our medical, dental, vision, life and disability plans, and our 401(k) plan. We generally do not provide perquisites or personal benefits to our Named Executive Officers.

401(k) Plan

We maintain a 401(k) plan for our employees who are 21 years of age or older. Our named executive officers are eligible to participate in the 401(k) plan on the same basis as our other employees. The 401(k) plan is intended to qualify as a tax-qualified plan under Section 401(k) of the Internal Revenue Code of 1986, as amended (the "Code").

Eligible employees may contribute of up 100% of his or her eligible compensation, subject to maximum amounts allowed under law. We currently provide discretionary matching contributions into the 401(k) plan on behalf of participants. Matching contributions vest immediately.

Role of Compensation Consultant in Executive Compensation

The Compensation Committee periodically reviews the Company's executive management compensation practices to consider and determine the competitiveness and effectiveness of those practices. In 2025, the Compensation Committee engaged Aon Radford to provide independent, objective analysis, advice and information regarding the Company's executive compensation practices, including the competitiveness of pay levels, executive compensation design, comparison with our peers in the industry, and other technical considerations.

Our Compensation Committee concluded that Aon Radford was independent under applicable Nasdaq listing standards and the engagement of Aon Radford does not raise any conflict of interest.

Policies and Practices Related to the Grant of Certain Equity Awards Close in Time to the Release of Material Nonpublic Information

While we do not have a formal written policy in place with regard to the timing of awards of options or similar awards in relation to the disclosure of material nonpublic information, our equity awards are generally granted on dates determined in advance. On limited occasions, our Board (or Compensation Committee, as appropriate) may grant equity awards outside of our annual grant cycle for new hires, promotions, recognition, retention or other purposes.

Our Board's general practice, and its practice for fiscal year 2025, has been to complete its annual executive compensation review and determine performance goals and target compensation for our executives, which coincides with the Company's regularly scheduled Board meetings; then equity awards are generally granted with an effective date of the Board meeting in which they were approved.

The Compensation Committee approves all equity award grants on or before the grant date and does not grant equity awards in anticipation of the release of material nonpublic information. Similarly, the Committee does not time the release of material nonpublic information based on equity award grant dates.

During 2025, we did not grant stock options to our named executive officers during any period beginning four business days before and ending one business day after the filing or furnishing of a Form 10-Q, 10-K or 8-K that discloses material nonpublic information.

Employment Agreements and Potential Payments Upon Certain Events

Employment Letter Agreements

We have entered into employment letter agreements with each of our Named Executive Officers (each, an "Employment Agreement"). Each Employment Agreement sets forth the Named Executive Officer's initial base salary, subject to review and adjustment by the Board from time to time. Each Named Executive Officer is also eligible to receive a discretionary annual bonus as determined by the Board or the Compensation Committee of the Board, in its sole discretion, conditioned on the Named Executive Officer being employed by the Company on the applicable bonus payment date. Such annual discretionary bonus may be paid, in the Named Executive Officer's discretion, in the form of cash or equity award (which equity award, if elected, will be immediately vested), consistent with bonuses paid to executives of similar grade at similarly situated companies in the biotechnology industry, subject to corporate and individual performance. Each Named Executive Officer is also eligible to participate in the Company's other employee benefit plans as in effect from time to time on the same basis as are generally made available to the Company's other senior executives.

Each Named Executive Officer's Employment Agreement also prohibits the disclosure or use of any proprietary or confidential information obtained by him as a result of his employment with the Company. Each Named Executive Officer is obligated not to compete with the Company during their employment and for a period of one year following their termination of employment with the Company. In addition, each Named Executive Officer's Employment Agreement contains restrictions related to the solicitation of, and interference with, customers, vendors and employees of the Company for a period of one year following termination of employment.

Payments Upon Termination or Change in Control

Garry Neil, M.D.

Pursuant to Dr. Neil's Employment Agreement, if Dr. Neil's employment is terminated by the Company without "Cause" or by Dr. Neil for "Good Reason" (each as defined in his Employment Agreement), in each case subject to him timely entering into and not revoking a general release of claims in a form acceptable to the Company, Dr. Neil will be eligible to receive:

(i) certain "Accrued Benefits" (as defined in the Neil Employment Agreement);
(ii) earned but unpaid bonus for the fiscal year preceding the year in which such termination occurs, based upon the achievement of Company goals as determined by the Compensation Committee of the Board, payable when such annual bonuses are paid to other executive employees of the Company;
(iii) continued payment of his base salary as in effect immediately prior to his termination for eighteen consecutive months following such termination;
(iv) the annual bonus earned in the year in which the termination occurs, based upon the achievement of Company goals as determined by the Compensation Committee of the Board, prorated to reflect completed days of employment during such year, payable when such annual bonuses are paid to other executive employees of the Company;
(v) full vesting of options awarded by the Company, in which case he will have twelve months from the date of his termination in which to exercise his options; and
(vi) if he timely elects and remains eligible for continued coverage under federal COBRA law or, if applicable, state insurance laws, the Company will pay Dr. Neil's COBRA or state continuation health insurance premiums until the earliest of (x) the twelve-month anniversary of his termination, (y) expiration of his continuation coverage under COBRA, or (z) the date when he is eligible for substantially equivalent health insurance, in each case subject to certain specified payment practices.

If a termination without cause occurs within six months of a change in control (as defined in the Company's 2016 Fourth Amended Plan), the payments pursuant to clauses (i-iii) shall be made promptly after its closing or his termination, whichever is later.

Other Named Executive Officers

Pursuant to the Employment Agreement with each of Mr. Boyd and Dr. Doyle, if Mr. Boyd's or Dr. Doyle's employment is terminated by the Company without "Cause" or by Mr. Boyd or Dr. Doyle for "Good Reason" (each as defined in the applicable Employment Agreement), in each case subject to the Named Executive Officer's timely entering into and not revoking a general release of claims in a form acceptable to the Company, such Named Executive Officer will be eligible to receive:

(i) certain "Accrued Benefits" (as defined in the applicable Employment Agreement);

(ii) earned but unpaid bonus for the fiscal year preceding the year in which such termination occurs, based upon the achievement of Company goals as determined by the Compensation Committee of the Board, payable when such annual bonuses are paid to other executive employees of the Company;

(iii) continued payment of their base salary as in effect immediately prior to the termination for nine consecutive months following such termination (extended to twelve months if such termination occurs on or within six months following a Change in Control, as defined in the applicable Employment Agreement);

(iv) the annual bonus earned in the year in which the termination occurs, based upon the achievement of Company goals as determined by the Compensation Committee of the Board, prorated to reflect completed days of employment during such year (increased to 100% of their bonus if such termination occurs on or within six months following a Change in Control), payable when such annual bonuses are paid to other executive employees of the Company;

(v) full vesting of options awarded by the Company, in which case such Named Executive Officer will have six months from the date of her termination in which to exercise their options; and

(vi) if the Named Executive Officer timely elects and remains eligible for continued coverage under federal COBRA law or, if applicable, state insurance laws, the Company will pay the Named Executive Officer's COBRA or state continuation health insurance premiums until the earliest of (x) the first anniversary of the termination, (y) expiration of continuation coverage under COBRA, or (z) the date when the Named Executive Officer is eligible for substantially equivalent health insurance, in each case subject to certain specified payment practices.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

The following table shows for the fiscal year ended December 31, 2025, certain information regarding outstanding equity awards at fiscal year-end for each of the Named Executive Officers. The market value of stock awards is based on the closing market price of our common stock of $18.16 per share on December 31, 2025.

			Option Awards				Stock Awards			
Name	Grant Date	Award Type	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Value of Shares or Units of Stock That Have Not Vested ($)	Number of Unearned Shares or Units That Have Not Vested (#)	Value Of Unearned Shares or Units That Have Not Vested ($)
Garry Neil, M.D.	2/3/2020	Stock Option[1]	278	—	$ 11,462.40	2/3/2030	—	—	—	—
	1/26/2021	Stock Option[1]	92	—	$ 9,561.60	1/26/2031	—	—	—	—
	3/8/2022	Stock Option[1]	327	21	$ 2,016.00	3/8/2032	—	—	—	—
	10/5/2022	Stock Option[2]	313	—	$ 952.80	10/5/2032	—	—	—	—
	2/13/2023	Stock Option[1]	297	121	$ 715.20	2/13/2033	—	—	—	—
	5/15/2023	Stock Option[2]	417	—	$ 660.00	5/15/2033	—	—	—	—
	8/13/2024	Stock Option[3]	218,925	281,475	$ 9.88	8/13/2034	—	—	—	—
	8/13/2024	Restricted Stock Unit[4]	—	—	$ —	—	129,733	$2,355,951	—	—
	1/28/2025	Stock Option[1]	—	411,000	$ 8.04	1/28/2035	—	—	—	—
	8/19/2025	Performance Stock Unit[5]	—	—	$ —	—	—	—	167,000	$3,032,720
Taylor Boyd	10/1/2025	Stock Option[1]	—	275,000	$ 12.96	10/1/2035	—	—	—	—
Mittie Doyle, M.D., FACR	7/15/2024	Stock Option[1]	82,875	151,125	$ 12.65	7/15/2034	—	—	—	—
	1/28/2025	Stock Option[1]	—	155,000	$ 8.04	1/28/2035	—	—	—	—
	8/19/2025	Performance Stock Unit[5]	—	—	$ —	—	—	—	72,500	$1,316,600

(1) One-fourth of the shares underlying the stock option shall vest and become exercisable on the first anniversary of the grant date, and the remaining three-fourths vest in equal monthly installments over the following 36 months, subject to the respective grantee providing continuous services to the Company.

(2) The shares underlying the stock option vested 100% on the first anniversary of the grant date.

(3) One-fourth of the shares underlying the stock option shall vest and become exercisable on March 28, 2025, and the remaining three-fourths vest in equal monthly installments over the following 36 months, subject to the respective grantee providing continuous services to the Company.

(4) The restricted stock unit awards will vest in three equal installments on each of March 28, 2025, March 28, 2026, and March 28, 2027. The market value of such awards is based on the closing market price of our common stock of $18.16 per share on December 31, 2025.

(5) These performance stock unit awards commence vesting following the achievement of the performance metric. The performance metric for the PSU Awards is based on the timing of data release and efficacy of the Company's Phase 2 LOTUS trial, and the achieved units may range from 0% to 150% of the target number depending on the level of achievement against the specified performance metric. Upon successful achievement of the performance metric, the number of units achieved will vest on the third anniversary of the grant date. The number of unearned units that have not vested in the table above assume 100% achievement of the performance metric, however, the number of units actually earned will depend upon actual achievement of the performance metric. The market value of such awards is based on the closing market price of our common stock of $18.16 per share on December 31, 2025.

DIRECTOR COMPENSATION

We have adopted a compensation policy for our non-employee directors (the "Director Compensation Policy"). The Director Compensation Policy was most recently amended effective June 17, 2025 after consultation with an independent, external compensation consultant, Radford, an Aon Company.

Under our Director Compensation Policy, we pay our non-employee directors a cash retainer for service on the Board and for service on each committee on which the director is a member. The chairman of the board and the chairman of each committee receive higher retainers for such service. These fees are payable in arrears in four equal quarterly installments on the last day of each quarter, provided that the amount of such payment is prorated for any portion of such quarter that the director was not serving on our Board or on such committee. The fees paid to non-employee directors in 2025 as a retainer for service on the Board and for service on each committee of the Board on which the director was a member were as follows:

	Member Annual Fee	Chairman Annual Fee
Board of Directors	$40,000	$80,000
Audit Committee	$10,000	$20,000
Compensation Committee	$6,500	$13,000
Nominating and Corporate Governance Committee	$5,000	$10,000
Science and Technology Advisory Committee	$7,500	$15,000

Each non-employee director may make an election to receive all or part of his or her annual cash retainer in the form of fully vested stock options to purchase shares of the Company's common stock. Elections must be made in multiples of 5% of an Eligible Director's aggregate cash retainer. The stock options will be granted on the date on which the cash would have otherwise been paid, with an exercise price per share equal to the last reported sale price of the common stock on the Nasdaq Capital Market on the date of grant or, if such grant date is not a trading date, on the last trading date prior to the grant date, and with a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service). The actual number of shares subject to the stock options will be determined so that the options have a "fair value" on the date of grant, using a Black-Scholes or binomial valuation model consistent with the methodology.

The Company reimburses non-employee directors for reasonable expenses incurred in connection with attending Board and committee meetings.

In addition, under our Director Compensation Policy, each of our non-employee directors is eligible to receive initial grants in connection with their appointment or election to the Board, as well as an annual grant on the date of each annual meeting. The number of shares underlying the stock option grants that non-employee directors are entitled to receive under the Director Compensation Policy are set forth in the table below. In 2025, each eligible non-employee director received the applicable grant unless noted below:

	Director (Non-Chairman of the Board)	Chairman of the Board	
Initial Grant[(1)]	40,200	59,000	(3)
Annual Grant[(2)]	20,100	29,500	

(1) The initial stock option grant vests in three substantially equal annual installments over three years commencing on the first anniversary of the grant date.

(2) The annual stock option grant vests in full on the first anniversary of the grant date, in each case, subject to continued service from the date of grant until the applicable vesting dates.

(3) The number of shares underlying the initial stock option grant for the chairman of the board was previously 50,000 options, which was the amount granted to Mr. Heffernan upon his appointment as chairman of the board. This amount was updated to 59,000 shares effective June 17, 2025.

The following table sets forth information regarding the total compensation to the Company's non-employee directors in 2025. The compensation amounts presented in the table below are historical and are not indicative of the amounts the Company may pay directors in the future. Directors who are also Company employees receive no additional compensation for their services as directors and are not included in the table below.

Name	Fees Earned or Paid in Cash[1] ($)	Option Awards[2][3] ($)	Stock Awards[2][3] ($)	Total ($)
Michael Heffernan[4]	$61,573	$448,005	$—	$509,578
June Almenoff, M.D., Ph.D.[5]	$47,917	$258,004	$61,810	$367,731
Mitchell Chan	$63,018	$70,973	$—	$133,991
Jonathan Goldman, M.D.	$57,500	$70,973	$—	$128,473
Rita Jain, M.D.[6]	$2,196	$175,383	$—	$177,579
Aaron Kantoff	$58,000	$70,973	$—	$128,973
Gilla Kaplan, Ph.D.	$55,982	$70,973	$—	$126,955
Kevin Lind[7]	$—	$456,488	$—	$456,488
Samantha Truex	$56,500	$70,973	$—	$127,473

(1) The amounts reflect cash fees earned for services rendered in fiscal year 2025.

(2) The amounts reflect the aggregate grant date fair value for option awards or stock awards granted or modified during 2025 in accordance with ASC 718, excluding the estimate of forfeitures. The assumptions used in valuing these options are described in Note 12 to our consolidated financial statements for the year ended December 31, 2025. Compensation will only be realized to the extent the market price of our common stock is greater than the exercise price of such option award. The amounts reported for Dr. Almenoff include modification expenses recognized in connection with the acceleration of her restricted stock units and acceleration and exercise period extension of her stock options, upon her resignation in October 2025.

(3) As of December 31, 2025, each director held options to purchase shares of the Company's common stock and outstanding stock awards as follows:

Name	Option Awards Held at December 31, 2025 (#)	Stock Awards Held at December 31, 2025 (#)
Michael Heffernan[4]	79,500	—
June Almenoff, M.D., Ph.D.[5]	44,791	—
Mitchell Chan	44,756	6,333
Jonathan Goldman, M.D.	36,500	6,333
Rita Jain, M.D.[6]	42,815	—
Aaron Kantoff	44,700	6,333
Gilla Kaplan, Ph.D.	44,818	6,333
Kevin Lind[7]	41,048	—
Samantha Truex	44,700	6,333

(4) Mr. Heffernan joined our Board in March 2025.

(5) Dr. Almenoff served on our Board through October 1, 2025. Upon her resignation from the Board, her outstanding options accelerated in full and the exercisability period was extended until September 30, 2026, and her restricted stock units accelerated in full.

(6) Dr. Jain joined our Board in June 2025.

(7) Mr. Lind joined our Board in October 2025.

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

EQUITY COMPENSATION PLAN INFORMATION

The following table contains certain information with respect to our equity compensation plan in effect as of December 31, 2025:

	(A)		(B)		(C)	
Plan category	**Number of Securities to be Issued Upon Exercise of Outstanding Options, Vesting of Restricted Stock Units, and Vesting of Performance Stock Units (#)**		**Weighted-Average Exercise Price of Outstanding Options ($)**		**Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans, excluding securities reflected in column (A) (#)**	
Equity compensation plans approved by stockholders	4,693,793	(1)	$12.52	(2)	860,965	(3)
Equity compensation plans not approved by stockholders	1,023,278	(4)	$15.56		811,000	(5)
Total	5,717,071		$13.20	(2)	1,671,965	

(1) The performance stock units included in this figure assumes the maximum 150% achievement of the performance metric, however, the number of units that actually vest will depend upon actual achievement of the performance metric and may range from 0% to 150% of the target number depending on the level of achievement against the specified performance metric.

(2) The weighted-average exercise price does not account for the shares issuable upon the vesting of outstanding restricted stock units and outstanding performance stock units, both of which have no exercise price. There were 387,064 unvested restricted stock units outstanding as of December 31, 2025. There were 738,750 unvested performance stock units outstanding as of December 31, 2025, which assumes the maximum 150% achievement of the performance metric, however, the number of units that actually vest will depend upon actual achievement of the performance metric and may range from 0% to 150% of the target number depending on the level of achievement against the specified performance metric.

(3) Reflects 327,806 shares of common stock available for future issuance under our Fourth Amended and Restated 2016 Equity Incentive Plan at December 31, 2025 (the "2016 Fourth Amended Plan") and 533,159 shares of common stock available for future issuance under our Amended and Restate 2016 Employee Stock Purchase Plan (the "ESPP"). During the term of the 2016 Fourth Amended Plan, the share reserve will automatically increase on the first trading day in January of each calendar year ending on (and including) January 1, 2034, by an amount equal to 5% of the total number of outstanding shares of common stock and Series C Preferred Stock (determined on an as-converted stock basis) plus all outstanding prefunded warrants to acquire shares of common stock (if any) as of December 31 of the preceding year. On January 1, 2026, pursuant to the terms of the 2016 Fourth Amended and Restated Plan, an additional 1,865,256 shares were made available for issuance. During the term of the ESPP, the share reserve will automatically increases by a number equal to 1% of the Company's outstanding shares of common stock and Series C Preferred Stock (determined on an as-converted basis) plus all outstanding prefunded warrants to acquire shares of common stock (if any), as of December 31 of the preceding calendar year. On January 1, 2026, pursuant to the terms of the ESPP, an additional 373,051 shares were made available for issuance.

(4) Consists of shares of common stock issuable upon exercise of outstanding stock options granted pursuant to the Nasdaq inducement grant exception as a component of employment compensation for an employee. The inducement grants were made as an inducement material to employees entering employment with us in accordance with Nasdaq Listing Rule 5635(c)(4).

(5) Reflects shares of common stock available for future issuance under our 2025 Inducement Award Plan. In September 2025, our board of directors adopted the 2025 Inducement Award Plan (the "Inducement Plan"). Grants under our Inducement Plan are awarded in accordance with Nasdaq Listing Rule 5635(c)(4). A total of 1,300,000 shares of our common stock were initially reserved for issuance under our Inducement Plan. As of December 31, 2025, there were 811,000 shares available for future issuance under the Inducement Plan. For more information, regarding the Inducement Plan, see Note 12 to our consolidated financial statements for the year ended December 31, 2025.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

Except as otherwise indicated, the following table sets forth information regarding the ownership of the Company's common stock as of March 16, 2026 by: (i) each director; (ii) our Named Executive Officers; (iii) all executive officers and directors of the Company as a group; and (iv) all other parties known by the Company to be beneficial owners of more than five percent of its common stock.

Applicable percentage ownership is based on 22,788,452 shares of our common stock outstanding as of March 16, 2026, together with applicable Series C Preferred Stock, options, restricted stock units and warrants, as the case may be, for each stockholder. Beneficial ownership is determined in accordance with the rules of the SEC, based on voting and investment power with respect to shares. Common stock subject to options, restricted stock units, warrants and Series C Preferred Stock that are currently exercisable, or exercisable within 60 days after March 16, 2026, are deemed outstanding for the purpose of computing the percentage ownership of the person holding those options, warrants, restricted stock units or Series C Preferred Stock, but are not deemed outstanding for computing the percentage ownership of any other person. Unless otherwise indicated, the address for each listed stockholder is c/o Avalo Therapeutics, Inc., 1500 Liberty Ridge Drive, Suite 321, Wayne, PA 19087.

	Beneficial Ownership [1]	
Beneficial Owner	**Number of Shares**	**Percent of Total**
5% Stockholders:		
BVF Partners, L.P. [2], [3]	2,348,661	9.99%
OrbiMed Advisors LLC [2], [4]	2,396,253	9.99%
RA Capital Management, L.P. [2], [5]	2,453,865	9.99%
FMR LLC [6]	2,125,819	9.33%
Nantahala Capital Management LLC [7]	1,235,000	5.42%
Directors and Named Executive Officers:		
Garry Neil, M.D. [8]	502,858	2.16%
Taylor Boyd	—	*
Mitchell Chan [9]	22,789	*
Mittie Doyle, M.D., FACR [10]	133,817	*
Jonathan Goldman, M.D. [11]	11,366	*
Michael Heffernan [12]	16,666	*
Rita Jain, M.D. [13]	2,615	*
Aaron Kantoff [14]	22,733	*
Gilla Kaplan, Ph.D. [15]	22,851	*
Kevin Lind [16]	848	*
Samantha Truex [17]	22,733	*
All current executive officers and directors as a group (14 persons) [18]	1,109,078	4.68%
*Less than one percent.		

(1) This table is based upon information supplied by our executive officers, directors, and principal stockholders, and on ownership reports filed by those persons with the SEC. Unless otherwise indicated in the footnotes to this table and subject to community property laws where applicable, the Company believes that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned.

(2) The number of shares beneficially owned includes shares of common stock issuable upon the conversion of shares of Series C Preferred Stock issued to certain holders in the AlmataBio Transaction and concurrent private placement in March 2024 (the "Series C Preferred Stock"), subject to beneficial ownership limitations, which does not permit that portion of the Series C Preferred Stock that would result in the holder and its affiliates owning, after conversion of the Series C Preferred Stock, a number of common stock in excess of the beneficial ownership limitation. Each share of the Company's Series C Preferred Stock is convertible into 1,000 shares of common stock.

(3) Based in part on a Schedule 13-G/A filed with the SEC on February 17, 2026 by BVF Partners, L.P. reporting ownership as of December 31, 2025 and based on the Company's knowledge from records. Each of the following are related entities and are subject to a beneficial ownership limitation of 9.99% on an aggregated basis: (i) Biotechnology Value Fund, L.P. ("BVF"), (ii) BVF I GP LLC ("BVF GP"), (iii) Biotechnology Value Fund II, L.P., ("BVF2"), (iv) BVF II GP LLC ("BVF2 GP"), (v) Biotechnology Value Trading Fund OS LP ("Trading Fund OS"), (vi) BVF Partners OS Ltd. ("Partners OS"), (vii) BVF GP Holdings LLC ("BVF GPH"), (viii) BVF Partners L.P. ("Partners"), (ix) BVF Inc., and (x) Mark N. Lampert. Consists of an aggregate (i) 1,622,661 shares of common stock; and (ii) 726.000 shares of Series C Preferred Stock, which is convertible into 726,000 shares of common stock, subject to a beneficial ownership limitation amount of 9.99%, which does not permit that portion of the Series C Preferred Stock that would result in the holder and its affiliates owning, after conversion of the Series C Preferred Stock, a number of common stock in excess of the beneficial ownership limitation. Each share of the Company's Series C Preferred Stock is convertible into 1,000 shares of common stock. BVF Inc. as the general partner of Partners, may be deemed to beneficially own the securities beneficially owned by Partners. Mark Lampert, as a director and officer of BVF Inc., may be deemed to beneficially own the securities beneficially owned by BVF Inc. BVF GP disclaims beneficial ownership of the shares of common stock beneficially owned by BVF. BVF2 GP disclaims beneficial ownership of the shares of common stock beneficially owned by BVF2. Partners OS disclaims beneficial ownership of the shares of common stock beneficially owned by Trading Fund OS. BVF GPH disclaims beneficial ownership of the shares of common stock beneficially owned by BVF and BVF2. Each of Partners, BVF Inc. and Mr. Lampert disclaims beneficial ownership of the shares of common stock beneficially owned by BVF, BVF2 and Trading Fund OS and held in the Partners Managed Account. BVF GP, BVF GPH, Partners, BVF Inc. and Mr. Lampert share voting and dispositive power over the shares of common stock beneficially owned by BVF. BVF GPH, Partners, BVF Inc. and Mr. Lampert share voting and dispositive power over the shares of common stock beneficially owned by BVF2. Partners, BVF Inc. and Mr. Lampert share voting and dispositive power over the shares of common stock beneficially owned by Trading Fund OS and held in the Partners Managed Account. The address for BVF, BVF GP, BVF2, BVF2 GP, BVF GPH, Partners, BVF Inc., and Mark Lampert is 44 Montgomery Street, 40th Floor, San Francisco, CA 94104. The address for Trading Fund OS and Partners OS is PO Box 309 Ugland House, Grand Cayman, KY1-1104, Cayman Islands.

(4) Based in part on a Schedule 13-G/A filed with the SEC on February 17, 2026 by OrbiMed Advisors LLC ("OrbiMed") reporting ownership as of December 31, 2025 and based on the Company's knowledge from records. Consists of 1,187,300 shares of common stock and 1,208,953 shares of common stock underlying the shares of Series C Preferred Stock. OrbiMed owns a total of 2,070.120 Series C Preferred Stock convertible into an aggregate of 2,070,120 shares of common stock, subject to beneficial ownership limitations of 9.99% on an aggregated basis, of which 1,208.953 Series C Preferred Stock convertible into 1,208,953 shares of common stock are included in the table above due to a beneficial ownership limitation. OrbiMed exercises investment and voting power over the shares of common stock through a management committee comprised of Carl L. Gordon, Sven H. Borho, and W. Carter Neild, each of whom disclaims beneficial ownership of the shares of common stock. The principal business address of the holder is Attn: General Counsel, 601 Lexington Avenue, 54th Floor, New York, NY 10022.

(5) Based in part on a Schedule 13-G/A filed with the SEC on February 17, 2026 by RA Capital Management, L.P. ("RA Capital"), Peter Kolchinsky, Rajeev Shah, RA Capital Healthcare Fund, L.P. (the "Fund") reporting ownership as of December 31, 2025 and based on the Company's knowledge from records. Consists of 662,968 shares of common stock and 1,790,897 shares of common stock underlying the shares of Series C Preferred Stock. RA Capital owns a total of 2,483.100 Series C Preferred Stock convertible into 2,483,100 shares of common stock, subject to beneficial ownership limitations of 9.99% on an aggregated basis of which 1,790.897 shares of Series C Preferred Stock convertible into 1,790,897 shares of common stock are included in the table above due to a beneficial ownership limitation. RA Capital Healthcare Fund GP, LLC is the general partner of the Fund. The general partner of RA Capital is RA Capital Management GP, LLC, of which Dr. Kolchinsky and Mr. Shah are the controlling persons. RA Capital serves as investment adviser for the Fund and may be deemed a beneficial owner, for purposes of Section 13(d) of the Act, of any securities of us held by the Fund. The Fund has delegated to RA Capital the sole power to vote and the sole power to dispose of all securities held in the Fund's portfolio, including the shares of our common stock reported herein. Because the Fund has divested voting and investment power over the reported securities it holds and may not revoke that delegation on less than 61 days' notice, the Fund disclaims beneficial ownership of the securities it holds for purposes of Section 13(d) of the Exchange Act.

As managers of RA Capital, Dr. Kolchinsky and Mr. Shah may be deemed beneficial owners, for purposes of Section 13(d) of the Exchange Act, of any of our securities beneficially owned by RA Capital. RA Capital, Dr. Kolchinsky, and Mr. Shah disclaim beneficial ownership of these securities other than for the purpose of determining their obligations under Section 13(d) of the Exchange Act, and shall not be deemed an admission that either RA Capital, Dr. Kolchinsky, or Mr. Shah is the beneficial owner of such securities for any other purpose. The principal business address of the holder is c/o RA Capital Management, L.P., 200 Berkeley Street, 18th Floor, Boston, MA 02116.

(6) Based in part on a Schedule 13-G filed with the SEC on March 6, 2026 by FMR LLC and Abigail P. Johnson reporting ownership as of February 27, 2026. Consists of 2,125,819 shares of common stock. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. The Schedule 13-G filed on March 6, 2026 by FMR LLC and Abigail P. Johnson reflects the securities beneficially owned, or that may be deemed to be beneficially owned, by FMR LLC, certain of its subsidiaries and affiliates, and other companies, or collectively referred to as the FMR Reporters. Such filing does not reflect securities, if any, beneficially owned by certain other companies whose beneficial ownership of securities is disaggregated from that of the FMR Reporters in accordance with Securities and Exchange Commission Release No. 34-39538 (January 12, 1998).The principal business address of the holder is 245 Summer Street, Boston, MA 02210.

(7) Based on a Schedule 13-F filed with the SEC on February 13, 2026 by Nantahala Capital Management, LLC reporting ownership as of December 31, 2025. Consists of 1,235,000 shares of common stock. The principal business address of the holder is 130 Main St. 2nd Floor, New Canaan, CT 06840.

(8) Consists of (i) 47,140 shares of common stock held by Dr. Neil, (ii) 390,852 shares issuable upon the exercise of options currently exercisable or exercisable within 60 days after March 16, 2026 and (iii) 64,866 shares issuable to Dr. Neil upon the vesting of restricted stock units within 60 days after March 16, 2026.

(9) Consists of (i) 3,167 shares of common stock held by Mr. Chan, (ii) 16,456 shares issuable to Mr. Chan upon the exercise of options currently exercisable or exercisable with 60 days after March 16, 2026 and (iii) 3,166 shares issuable to Mr. Chan upon the vesting of restricted stock units within 60 days after March 16, 2026.

(10) Consists of (i) 3,622 shares of common stock held by Dr. Doyle and (ii) 130,195 shares issuable to Dr. Doyle upon the exercise of options currently exercisable or exercisable with 60 days after March 16, 2026.

(11) Consists of (i) 8,200 shares issuable to Dr. Goldman upon the exercise of options currently exercisable or exercisable with 60 days after March 16, 2026 and (ii) 3,166 shares issuable to Dr. Goldman upon the vesting of restricted stock units within 60 days after March 16, 2026.

(12) Consists of 16,666 shares issuable to Mr. Heffernan upon the exercise of options currently exercisable or exercisable with 60 days after March 16, 2026.

(13) Consists of 2,615 shares issuable to Dr. Jain upon the exercise of options currently exercisable or exercisable with 60 days after March 16, 2026.

(14) Consists of (i) 3,167 shares of common stock held by Mr. Kantoff, (ii) 16,400 shares issuable to Mr. Kantoff upon the exercise of options currently exercisable or exercisable with 60 days after March 16, 2026 and (iii) 3,166 shares issuable to Mr. Kantoff upon the vesting of restricted stock units within 60 days after March 16, 2026.

(15) Consists of (i) 3,167 shares of common stock held by Dr. Kaplan, (ii) 16,518 shares issuable to Dr. Kaplan upon the exercise of options currently exercisable or exercisable within 60 days after March 16, 2026 and (iii) 3,166 shares issuable to Dr. Kaplan upon the vesting of restricted stock units within 60 days after March 16, 2026.

(16) Consists of 848 shares issuable to Mr. Lind upon the exercise of options currently exercisable or exercisable within 60 days after March 16, 2026.

(17) Consists of (i) 3,167 shares of common stock held by Ms. Truex, (ii) 16,400 shares issuable to Ms. Truex upon the exercise of options currently exercisable or exercisable with 60 days after March 16, 2026 and (iii) 3,166 shares issuable to Ms. Truex upon the vesting of restricted stock units within 60 days after March 16, 2026.

(18) Consists of (i) 87,057 shares of common stock, (ii) 917,125 shares issuable upon the exercise of options currently exercisable or exercisable within 60 days after March 16, 2026 and (iii) 104,896 shares issuable upon the vesting of restricted stock units within 60 days after March 16, 2026.

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

RELATED PERSON TRANSACTIONS POLICY AND PROCEDURES

In 2015, in connection with our initial public offering, our Board adopted a written related person transaction policy to set forth policies and procedures for the review and approval or ratification of related person transactions. The policy was amended on November 5, 2021. This policy covers any transaction, including, for the avoidance of doubt, transactions constituting a sale or conveyance of stock and/or stock derivatives, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which the Company is, was or will be a participant, and the amount involved exceeds $120,000 with one of our executive officers, directors, director nominees or 5% stockholders, or their immediate family members, each of whom we refer to as a "related person."

If a related person proposes to enter into such a transaction, arrangement or relationship, which we refer to as a "related person transaction," the related person must report the proposed related person transaction to our Audit Committee. The policy calls for the proposed related person transaction to be reviewed and, if deemed appropriate, approved by our Audit Committee. Whenever practicable, the reporting, review and approval will occur prior to entry into the transaction. If advance review and approval is not practicable, the Audit Committee will review, and, in its discretion, may ratify the related person transaction.

A related person transaction reviewed under the policy will be considered approved or ratified if it is authorized by the Audit Committee after full disclosure of the related person's interest in the transaction. As appropriate for the circumstances, the Audit Committee will review and consider:

- the interests, direct or indirect, of any related person in the transaction;
- the purpose of the transaction;
- the proposed aggregate value of such transaction, or, in the case of indebtedness, that amount of principal that would be involved;
- the risks, costs and benefits to the Company;
- the availability of other sources of comparable products or services;
- management's recommendation with respect to the proposed related person transaction;
- the terms of the transaction;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The Audit Committee, in approving or rejecting any related person transactions involving the sale and/or conveyance of the Company's stock or stock derivatives to a significant shareholder holding 20% or more of (a) any class of the Company's voting securities, or (b) the Company's voting power, or their immediate family member and/or affiliates, shall consider whether such transaction involves a change of control.

Our Audit Committee will approve only those related person transactions that, in light of known circumstances, are in, or are not inconsistent with, the best interests of the Company and its stockholders, as the Audit Committee determines in the good faith exercise of its discretion.

In addition to the transactions that are excluded by the instructions to the SEC's related person transaction disclosure rule, our Board has determined that the following transactions do not create a material direct or indirect interest on behalf of related persons and, therefore, are not related person transactions for purposes of this policy:

- transactions involving compensation for services provided to the Company as an employee, consultant or director; and
- a transaction, arrangement or relationship in which a related person's participation is solely due to the related person's position as a director of an entity that is participating in such transaction, arrangement or relationship.

CERTAIN RELATED PERSON TRANSACTIONS

The following sets forth all transactions since January 1, 2024 to which the Company has been or is a participant, including currently proposed transactions, in which the amount involved in the transaction exceeds $120,000 and in which any of our directors, executive officers or beneficial holders of more than 5% of any class of our capital stock, or any immediate family member of, or person sharing the household with any of these individuals, had or has a direct or indirect material interest.

Indemnification Agreements

We have entered into indemnification agreements with each of our directors and certain of our executive officers. These agreements require us to indemnify these individuals and, in certain cases, affiliates of such individuals, to the fullest extent permitted under Delaware law against liabilities that may arise by reason of their service to the Company, and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified.

Employment Agreements

We have entered into employment agreements with our current executive officers. For more information regarding these agreements, please see "Executive Compensation – Narrative to Summary Compensation Table – Employment Arrangements and Potential Payments Upon Certain Events" above.

Stock Option and Restricted Stock Unit Grants to Executive Officers and Directors

We have granted stock options to our named executive officers and directors, as well as restricted stock units and performance stock units to certain named executive officers and directors as more fully described in "Executive Compensation" and "Director Compensation" above.

Consulting Agreement with Northbrook Consulting

The Company appointed Jennifer Riley as its Chief Strategy Officer, effective January 1, 2025. Prior to Ms. Riley's appointment to Chief Strategy Officer, the Company engaged Ms. Riley as a consultant through Northbrook Consulting, LLC ("Northbrook") to provide consulting services from July 2024 to December 2024. Ms. Riley is the founder and sole member of Northbrook. Northbrook received aggregate total payments of approximately $188,000 for consulting services it provided to the Company over the course of its engagement with the Company. Northbrook's business relationship with the Company ended on December 31, 2024, and Northbrook is not due any additional payment from the Company for services rendered. There have been no other transactions in which the Company has participated and in which Ms. Riley had a direct or indirect material interest.

DIRECTOR INDEPENDENCE

After review of all relevant identified transactions or relationships between each director, or any of his or her family members, and the Company, its senior management and its independent auditors, the Board has affirmatively determined that the following directors are independent directors within the meaning of the applicable Nasdaq listing standards and the independence criteria set forth in our Corporate Governance Guidelines: Mr. Heffernan, Mr. Chan, Dr. Goldman, Dr. Jain, Mr. Kantoff, Dr. Kaplan, Mr. Lind and Ms. Truex. In making this determination, the Board found that none of these directors or nominees for director had a material or other disqualifying relationship with the Company.

In making those independence determinations, the Board took into account certain relationships and transactions that occurred in the ordinary course of business between the Company and entities with which some of its directors are or have been affiliated. The Board considered all relationships and transactions that occurred during any 12-month period within the last three fiscal years, including the participation by our directors and entities affiliated with our directors in various financing transactions with the Company, and determined that there were no relationships that would interfere with their exercise of independent judgment in carrying out their responsibilities as directors.

Item 14. Principal Accounting Fees and Services.

The following table represents aggregate fees billed to the Company for the fiscal years ended December 31, 2025 and 2024, by Ernst & Young LLP ("EY"), the Company's principal accountant. All fees described below were pre-approved by the Audit Committee.

	Fiscal Year Ended December 31,	
	2025	2024
Audit fees[1]	$ 684,000	$ 942,489
Audit-related fees[2]	18,000	18,000
Tax fees[3]	—	—
All other fees[4]	1,230	1,995
Total	$ 703,230	$ 962,484

[1] Audit fees consisted of audit work performed in the audit of our financial statements, as well as work that generally only the independent registered public accounting firm can reasonably be expected to provide, such as accounting consultations billed as audit services, and consents and assistance with and review of documents filed with the SEC. The increased audit fees in 2024 is largely attributable to the engagement of EY to audit the financial statements of AlmataBio, Inc. as of December 31, 2024 and for the period from April 28, 2023 to December 31, 2023, as filed in the Current Report on Form 8-K/A filed on June 3, 2024.

[2] Audit-related fees consist of consulting and advisory fees related to potential acquisitions and strategic transactions and audit fees related to acquired entities.

[3] Tax services principally include tax compliance, tax advice and tax planning.

[4] All other fees consisted of all other products and services provided by the independent registered public accounting firm that are not reflected in any of the previous categories, such as the use of online accounting research tools.

PRE-APPROVAL POLICIES AND PROCEDURES

The Audit Committee has adopted a policy and procedures for the pre-approval of audit and non-audit services rendered by the Company's independent registered public accounting firm, EY. The policy generally pre-approves specified services in the defined categories of audit services, audit-related services and tax services up to specified amounts. Pre-approval may also be given as part of the Audit Committee's approval of the scope of the engagement of the independent auditor or on an individual, explicit, case-by-case basis before the independent auditor is engaged to provide each service. The pre-approval of services may be delegated to one or more of the Audit Committee's members, but the decision must be reported to the full Audit Committee at its next scheduled meeting.

The Audit Committee has determined that the rendering of non-audit services by EY is compatible with maintaining the principal accountant's independence for the period of time during which it has served as our independent auditor.

PART IV

Item 15. Exhibits; Financial Statement Schedules.

(a) *Documents filed as part of this report.*

1. The following consolidated financial statements of Avalo Therapeutics, Inc. and Report of Ernst & Young LLP, Independent Registered Public Accounting Firm, are included in this report:

2. List of financial statement schedules. All schedules are omitted because they are not applicable or the required information is shown in the financial statements described above.

3. List of Exhibits required by Item 601 of Regulation S-K. See part (b) below.

(b) *Exhibits.*

The following is a list of exhibits filed as part of this Annual Report on Form 10-K. Where so indicated by footnote, exhibits that were previously filed are incorporated by reference. For exhibits incorporated by reference, the location of the exhibit in the previous filing is indicated.

Exhibit Number	Description of Exhibit
2.1	Agreement and Plan of Merger and Reorganization, dated March 27, 2024, by and among Avalo Therapeutics, Inc., Project Athens Merger Sub, Inc., Second Project Athens Merger Sub, LLC, and AlmataBio, Inc. (incorporated by reference to Exhibit 2.1 to the Form 8-K filed on March 28, 2024).
3.1.1	Amended and Restated Certificate of Incorporation of Cerecor Inc. (incorporated by reference to Exhibit 3.1.2 to the Current Report on Form 8-K filed on May 17, 2018).
3.1.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cerecor Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on August 26, 2021).
3.1.3	Certificate of Amendment to the Company's Amended and Restated Certificate of Incorporation, as amended, dated July 5, 2022 and effective July 7, 2022 (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on July 7, 2022).
3.1.4	Certificate of Amendment to the Company's Amended and Restated Certificate of Incorporation, as amended, dated December 22, 2023 and effective December 28, 2023 (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on December 28, 2023).
3.1.5	Form of Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of Cerecor Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on April 28, 2017).

3.1.6	Form of Certificate of Designation of Series B Non-Voting Convertible Preferred Stock of Cerecor Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on December 27, 2018).
3.1.7	Certificate of Designation for Avalo Therapeutics, Inc.'s Series C Preferred Stock filed with the Secretary of State of Delaware on March 27, 2024 (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on March 28, 2024).
3.1.8	Certificate of Designation for Avalo Therapeutics, Inc.'s Series D Preferred Stock filed with the Secretary of State of Delaware on March 27, 2024 (incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K filed on March 28, 2024).
3.1.9	Certificate of Designation for Avalo Therapeutics, Inc.'s Series E Preferred Stock filed with the Secretary of State of Delaware on March 27, 2024 (incorporated by reference to Exhibit 3.3 to the Current Report on Form 8-K filed on March 28, 2024).
3.2	Fifth Amended and Restated Bylaws of Avalo Therapeutics, Inc (incorporated by reference to Exhibit 3.2 to the Form 10-K filed on March 29, 2024).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.3 to the Registration Statement on Form S-8 filed on May 20, 2016).
4.2.1	Warrant to Purchase Common Stock (Loan A) issued June 4, 2021 by Cerecor, Inc. to Horizon Technology Finance Corporation (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed on June 8, 2021).
4.2.2	Warrant to Purchase Common Stock (Loan B) issued June 4, 2021 by Cerecor, Inc. to Horizon Technology Finance Corporation (incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed on June 8, 2021).
4.2.3	Warrant to Purchase Common Stock (Loan C) issued June 4, 2021 by Cerecor, Inc. to Horizon Technology Finance Corporation (incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K filed on June 8, 2021).
4.2.4	Warrant to Purchase Common Stock (Loan D) issued June 4, 2021 by Cerecor, Inc. to Powerscourt Investments XXV, LP (incorporated by reference to Exhibit 4.4 to the Current Report on Form 8-K filed on June 8, 2021).
4.2.5	Warrant to Purchase Common Stock (Loan E) issued June 4, 2021 by Cerecor, Inc. to Horizon Technology Finance Corporation (incorporated by reference to Exhibit 4.5 to the Current Report on Form 8-K filed on June 8, 2021).
4.2.6	Warrant to Purchase Common Stock (Loan F) issued June 4, 2021 by Cerecor, Inc. to Horizon Technology Finance Corporation (incorporated by reference to Exhibit 4.6 to the Current Report on Form 8-K filed on June 8, 2021).
4.2.7	Warrant to Purchase Common Stock (Loan G) issued June 4, 2021 by Cerecor, Inc. to Horizon Technology Finance Corporation (incorporated by reference to Exhibit 4.7 to the Current Report on Form 8-K filed on June 8, 2021).
4.2.8	Warrant to Purchase Common Stock (Loan H) issued June 4, 2021 by Cerecor, Inc. to Horizon Technology Finance Corporation (incorporated by reference to Exhibit 4.8 to the Current Report on Form 8-K filed on June 8, 2021).

4.3	Description of Registered Securities (incorporated by reference to Exhibit 4.5 to the Annual Report on Form 10-K for the year ended December 31, 2024).
4.4	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed on March 28, 2024.)
10.1.1 *	License Agreement, dated as of November 12, 2014, between Medgenics Medical Israel Ltd. and The Children's Hospital of Philadelphia (previously filed as Exhibit 10.29 to Aevi's Annual Report on Form 10-K for the year ended December 31, 2014 and incorporated herein by reference).
10.1.2 *	Amendment No. 1 to License Agreement, dated as of February 14, 2017, by and between The Children's Hospital of Philadelphia and Medgenics Medical Israel Ltd. (previously filed as Exhibit 10.1 to Aevi's Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 and incorporated herein by reference).
10.1.3	Amendment No. 2 to License Agreement, dated March 29, 2019, by and between Medgenics Medical Israel Ltd. and the Children's Hospital of Philadelphia. (previously filed as Exhibit 10.4 to Aevi's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019 and incorporated herein by reference).
10.1.4	Letter Agreement, dated March 29, 2019, by and between the Company and the Children's Hospital of Philadelphia (previously filed as Exhibit 10.6 to Aevi's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019 and incorporated herein by reference).
10.1.5	Amendment No. 3 to License Agreement, dated as of August 12, 2019, by and between Medgenics Medical Israel Ltd. and The Children's Hospital of Philadelphia (previously filed as Exhibit 10.3 to Aevi's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 and incorporated herein by reference).
10.1.6	Amendment No. 6 to License Agreement, dated as of November 13, 2020, by and between Medgenics Medical Israel Ltd. and The Children's Hospital of Philadelphia (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on November 20, 2020).
10.2.1 **	Exclusive License Agreement, dated as of July 15, 2019, by and between Aevi Genomic Medicine, Inc. and OSI Pharmaceuticals, LLC (previously filed as Exhibit 10.1 to Aevi's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 and incorporated herein by reference).
10.2.2 **	Royalty Agreement, dated as of July 19, 2019, between and among Aevi Genomic Medicine, Inc., Michael F. Cola Joseph J. Grano, Jr., Kathleen Jane Grano, Joseph C. Grano, The Grano Children's Trust, Joseph C. Grano, trustee and LeoGroup Private Investment Access, LLC on behalf of Garry A. Neil (previously filed as Exhibit 10.2 to Aevi's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 and incorporated herein by reference).
10.3.1 *	Clinical Development and Option Agreement, by and between Medgenics, Inc. and Kyowa Hakko Kirin Co., Ltd., dated June 6, 2016 (previously filed as Exhibit 10.1 to Aevi's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 and incorporated herein by reference).
10.3.2 **	Amended and Restated Clinical Development and Option Agreement, dated May 28, 2020, by and between Aevi Genomic Medicine, LLC and Kyowa Kirin Co., Ltd., formerly known as Kyowa Kirin Co., Ltd. (incorporated by reference to Exhibit 10.28 to the Quarterly Report on Form 10-Q filed on August 6, 2020).

10.3.3 **	License Agreement, dated March 25, 2021, by and between Cerecor Inc. and Kyowa Hakko Kirin Co., Ltd (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed on May 13, 2021).
10.4.1	License Agreement, dated November 25, 2019, by and between Flame Biosciences LLC and Eli Lilly and Company (incorporated by reference to Exhibit 10.2 to the Form 10-Q filed on May 13, 2024).
10.4.2	First Amendment to License Agreement, dated February 2, 2021, by and between Flame Biosciences LLC and Eli Lilly and Company (incorporated by reference to Exhibit 10.3 to the Form 10-Q filed on May 13, 2024).
10.4.3	Asset Purchase Agreement, dated December 6, 2023, by and among AlmataBio, Inc., Leap Therapeutics, Inc., and Flame Biosciences LLC. (incorporated by reference to Exhibit 10.1 to the Form 10-Q filed on May 13, 2024).
10.5.1 *	License Agreement, dated July 29, 2022, by and between Apollo AP43 Limited and Avalo Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed on November 7, 2022).
10.5.2 *	Purchase Agreement, dated November 4, 2022, by and between ES Therapeutics, LLC and Avalo Therapeutics, Inc. (incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q filed on November 7, 2022).
10.6.1	Sales Agreement, dated June 5, 2025, between Avalo Therapeutics, Inc. and TD Securities (USA) LLC (incorporated by reference to Exhibit 1.1 to the Current Report on Form 8-K filed on June 5, 2025).
10.7.1	Securities Purchase Agreement, dated March 27, 2024, by and among Avalo Therapeutics, Inc. and the investors signatory thereto (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on March 28, 2024).
10.8 +	Avalo Therapeutics, Inc. Amended and Restated 2016 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on August 14, 2024).
10.9 +	Avalo Therapeutics, Inc. Fourth Amended and Restated 2016 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on August 14, 2024).
10.10+	Amended and Restated Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed on June 18, 2025).
10.11	Form of Director Indemnification Agreement (incorporated by reference to Exhibit 10.14 to the Annual Report on Form 10-K fore the year ended December 31, 2024).
10.12.1 +	Employment Agreement, effective February 3, 2020, by and between Cerecor Inc. and Garry A. Neil (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed on February 3, 2020).
10.12.2 +	Letter Agreement, dated February 18, 2022, by and between Avalo Therapeutics, Inc. and Garry Neil (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on February 18, 2022).

10.13.1 +	Employment Agreement, dated September 26, 2019, by and between Cerecor Inc. and Christopher Sullivan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on April 27, 2020).
10.13.2 +	Letter Agreement, dated April 23, 2020, by and between Cerecor Inc. and Christopher Sullivan (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on April 27, 2020).
10.13.3 +	Letter Agreement, dated February 18, 2022, by and between Avalo Therapeutics, Inc. and Christopher Sullivan (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on February 18, 2022).
10.14.1 +	Employment Agreement, dated May 6, 2024, by and between Avalo Therapeutics, Inc. and Paul Varki (incorporated by reference to Exhibit 10.1 on the Current Report on Form 8-K filed on June 24, 2024).
10.14.2 +	Amendment to Employment Agreement, dated May 10, 2024, by and between Avalo Therapeutics, Inc. and Paul Varki (incorporated by reference to Exhibit 10.2 on the Current Report on Form 8-K filed on June 24, 2024).
10.15 +	Employment Agreement, dated June 1, 2024, by and between Avalo Therapeutics, Inc. and Mittie Doyle (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on July 16, 2024).
10.16 +	Employment Agreement, dated November 21, 2024, by and between Avalo Therapeutics, Inc. and Jennifer Riley (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on January 2, 2025).
10.17+	Avalo Therapeutics, Inc. 2025 Inducement Award Plan (incorporated by reference to Exhibit 10.2 to the Current Report on Form 10-Q filed on November 6, 2025).
10.18+	Employment Agreement, dated September 29, 2025 by and between Avalo Therapeutics, Inc. and Taylor Boyd (incorporated by reference to Exhibit 10.1. to the Current Report on Form 8-K filed on October 1, 2025).
19.1	Insider Trading Policy, dated May 15, 2018 (incorporated by reference to Exhibit 19.1 to the Annual Report on Form 10-K for the year ended December 31, 2024).
21.1	List of Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Annual Report on Form 10-K for the year ended December 31, 2024).
23.1 ‡	Consent of Ernst & Young LLP, independent registered public accounting firm.
31.1 ‡	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2 ‡	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1 # ‡	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

97.1	Avalo Therapeutics, Inc. Incentive Compensation Clawback Policy, effective as of November 21, 2023 (incorporated by reference to Exhibit 97.1 to the Annual Report on Form 10-K for the year ended December 31, 2024).
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File, formatted in inline XBRL (included in Exhibit 101).

---

* Confidential treatment has been requested for portions of this exhibit.

** Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10).

+ Management contract or compensatory agreement.

‡ Filed herewith.

This certification is being furnished solely to accompany this 10-K pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 16. 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Avalo Therapeutics, Inc.

/s/ Christopher Sullivan

Christopher Sullivan
Chief Financial Officer

Date: March 23, 2026

Pursuant to the requirements of the Securities and Exchange Act of 1934, this report 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/ Garry Neil, M.D. **Garry Neil, M.D.**	Chief Executive Officer and Director *(Principal Executive Officer)*	March 23, 2026
/s/ Christopher Sullivan **Christopher Sullivan**	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 23, 2026
/s/ Michael Heffernan **Michael Heffernan**	Director and Chairman	March 23, 2026
/s/ Mitchell Chan **Mitchell Chan**	Director	March 23, 2026
/s/ Jonathan Goldman, M.D. **Jonathan Goldman, M.D.**	Director	March 23, 2026
/s/ Rita Jain, M.D. **Rita Jain, M.D.**	Director	March 23, 2026
/s/ Aaron Kantoff **Aaron Kantoff**	Director	March 23, 2026
/s/ Gilla Kaplan, Ph.D. **Gilla Kaplan, Ph.D.**	Director	March 23, 2026
/s/ Kevin Lind **Kevin Lind**	Director	March 23, 2026
/s/ Samantha Truex **Samantha Truex**	Director	March 23, 2026

AVALO THERAPEUTICS, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Avalo Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Avalo Therapeutics, Inc. and subsidiaries (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, mezzanine and 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 "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at 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 U.S. generally accepted accounting principles.

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.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Valuation of Derivative Instrument

Description of the Matter

As more fully described in Note 6 of the consolidated financial statements, as of December 31, 2025, the Company recorded an $18.0 million derivative liability related to future milestone and royalty payments, which is measured at fair value. To determine the fair value of the derivative liability the Company applied a combination of a scenario-based method and an option pricing method using observable and unobservable market data for inputs, including the estimated amount and timing of the projected payments, the probability of each milestone's success and the discount rate.

Auditing management's estimate of the fair value of the derivative liability involved subjective auditor judgment because the fair value calculations were sensitive to changes in assumptions described above, and certain inputs used in the determination of the fair value were based on unobservable data, including, but not limited to, the estimated amount and timing of the projected payments, the probability of each milestone's success and the discount rate.

How We Addressed the Matter in Our Audit

Our audit procedures included, among others, evaluating the methodology used in the valuation model and the significant assumptions described above. We compared the significant assumptions to current industry and market trends, to guideline companies within the same industry, and to other relevant data. We involved our valuation specialists to assist in the evaluation, including to assess whether the methodology used in developing the estimate was consistent with valuation practice given the characteristics of the derivative being measured and to develop an independent valuation of the instrument. We also analyzed certain significant assumptions, including the discount rate and probability of each milestone's success, to evaluate the change in the fair value that would result from changes in the assumptions.

Clinical Trial Prepaid and Accrued Expenses

Description of the Matter

As discussed in Note 2 of the consolidated financial statements, depending on the timing of payments to service providers, the Company records clinical trial prepaid or accrued expenses based on management's estimates of the work performed under the agreements.
Auditing the Company's accounting for clinical trial prepaid and accrued expenses is challenging due to the fact that information necessary to estimate the clinical trial prepaid and accrued expenses is accumulated from multiple sources. The determination of the clinical trial prepaid and accrued expenses when the Company has either not been invoiced or has not received information regarding actual costs incurred requires evaluation of the extent of completion of the services.

How We Addressed the Matter in Our Audit

Our audit procedures included, among others, confirming the completeness of the terms and conditions of certain significant service agreements directly with the vendor. We tested the completeness and accuracy of the Company's clinical trial prepaid and accrued expense balances through verification of significant inputs, such as costs incurred and invoices paid, to the terms and conditions of the underlying agreements. We met with clinical operations personnel outside of the accounting department to discuss the basis for assumptions used in estimating the clinical trial prepaid and accrued expense balances. We performed a hindsight analysis of invoices received subsequent to the balance sheet date and compared them to the Company's estimates.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2013.

Jericho, New York
March 23, 2026

AVALO THERAPEUTICS, INC. and SUBSIDIARIES

Consolidated Balance Sheets
(In thousands, except share and per share data)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 15,858	$ 134,546
Short-term investments	82,478	—
Prepaid expenses and other current assets	6,913	4,325
Restricted cash, current portion	37	19
Total current assets	105,286	138,890
Property and equipment, net	460	1,209
Goodwill	10,502	10,502
Restricted cash, net of current portion	210	131
Total assets	$ 116,458	$ 150,732
Liabilities, mezzanine equity and stockholders' equity		
Current liabilities:		
Accounts payable	$ 137	$ 283
Accrued expenses and other current liabilities	12,803	6,317
Derivative liability, current	—	360
Total current liabilities	12,940	6,960
Royalty obligation	2,000	2,000
Deferred tax liability, net	434	270
Derivative liability, non-current	18,000	8,120
Other long-term liabilities	35	350
Total liabilities	33,409	17,700
Mezzanine equity:		
Series D Preferred Stock—$0.001 par value; 1 share of Series D Preferred Stock authorized at December 31, 2025 and December 31, 2024; 1 share of Series D Preferred Stock issued and outstanding at December 31, 2025 and 2024	—	—
Series E Preferred Stock—$0.001 par value; 1 share of Series E Preferred Stock authorized at December 31, 2025 and December 31, 2024; 1 share of Series E Preferred Stock issued and outstanding at December 31, 2025 and December 31, 2024	—	—
Stockholders' equity:		
Common stock—$0.001 par value; 200,000,000 shares authorized at December 31, 2025 and December 31, 2024; 18,512,757 and 10,471,934 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	18	10
Series C Preferred Stock—$0.001 par value; 34,326 shares of Series C Preferred Stock authorized at December 31, 2025 and December 31, 2024, 18,792 and 24,896 shares of Series C Preferred Stock issued and outstanding at December 31, 2025 and December 31, 2024, respectively	—	—
Additional paid-in capital	531,485	503,285
Accumulated other comprehensive income	68	—
Accumulated deficit	(448,522)	(370,263)
Total stockholders' equity	83,049	133,032
Total liabilities, mezzanine equity and stockholders' equity	$ 116,458	$ 150,732

See accompanying notes to the consolidated financial statements.

AVALO THERAPEUTICS, INC. and SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except per share data)

	Year Ended December 31,	
	2025	2024
Revenues:		
Product revenue, net	$ 59	$ 441
Total revenues, net	59	441
Operating expenses:		
Cost of product sales	—	(366)
Research and development	50,084	24,437
Acquired in-process research and development	—	27,641
General and administrative	22,900	17,241
Total operating expenses	72,984	68,953
Loss from operations	(72,925)	(68,512)
Other (expense) income:		
Change in fair value of derivative liability	(9,520)	(2,930)
Interest income, net	4,351	3,312
Excess of initial warrant fair value over private placement proceeds	—	(79,276)
Change in fair value of warrant liability	—	121,611
Private placement transaction costs	—	(9,220)
Total other (expense) income, net	(5,169)	33,497
Loss before income taxes	(78,094)	(35,015)
Income tax expense	165	114
Net loss	$ (78,259)	$ (35,129)
Net loss per share of common stock - basic	$ (5.84)	$ (7.94)
Net loss per share of common stock - diluted	$ (5.84)	$ (20.91)
Weighted average common shares outstanding - basic	13,404,830	4,426,149
Weighted average common shares outstanding - diluted	13,404,830	7,496,389
Comprehensive loss		
Net loss	$ (78,259)	$ (35,129)
Other comprehensive income:		
Unrealized income on investments, net	68	—
Comprehensive loss	$ (78,191)	$ (35,129)

See accompanying notes to the consolidated financial statements.

AVALO THERAPEUTICS, INC. and SUBSIDIARIES
Consolidated Statements of Mezzanine and Stockholders' Equity
(In thousands, except share amounts)

	Mezzanine preferred stock		Common stock		Series C preferred stock		Additional paid-in	Accumulated other	Accumulated	Total stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	capital	comprehensive income	deficit	equity
Balance, December 31, 2023	—	$ —	801,746	$ 1	—	$ —	$ 342,437	$ —	$ (335,134)	$ 7,304
Impact of reverse split fractional share round-up	—	—	60,779	—	—	—	—	—	—	—
Issuance of common stock pursuant to AlmataBio Transaction	—	—	171,605	—	—	—	815	—	—	815
Issuance of Series C Preferred Stock pursuant to AlmataBio Transaction	2,412	11,457	—	—	—	—	—	—	—	—
Issuance of Series C Preferred Stock in private placement	19,946	—	—	—	—	—	—	—	—	—
Issuance of Series D Preferred Stock in private placement	1	—	—	—	—	—	—	—	—	—
Issuance of Series E Preferred Stock in private placement	1	—	—	—	—	—	—	—	—	—
Retirement of Series C Preferred Stock in exchange for issuance of common stock	(8,648)	(9,799)	—	—	—	—	—	—	—	—
Issuance of common stock in exchange for retirement of Series C Preferred Stock	—	—	8,648,244	8	—	—	9,790	—	—	9,798
Issuance of common shares pursuant to warrant exercises	—	—	781,259	1	—	—	9,646	—	—	9,647
Issuance of Series C Preferred Stock pursuant to warrant exercises	—	—	—	—	11,186	—	133,019	—	—	133,019
Reclassification of Series C Preferred Stock from mezzanine equity to permanent equity	(13,710)	(1,658)	—	—	13,710	—	1,658	—	—	1,658
Shares purchased through employee stock purchase plan	—	—	8,301	—	—	—	68	—	—	68
Stock-based compensation	—	—	—	—	—	—	5,852	—	—	5,852
Net loss	—	—	—	—	—	—	—	—	(35,129)	(35,129)
Balance, December 31, 2024	2	$ —	10,471,934	$ 10	$ 24,896	$ —	$ 503,285	$ —	$ (370,263)	$ 133,032
Issuance of common stock in exchange for retirement of Series C Preferred Stock	—	—	6,103,560	6	(6,104)	—	(6)	—	—	—
Issuance of common stock pursuant to ATM Program, net	—	—	1,658,333	2	—	—	14,298	—	—	14,300
Vesting of Restricted Stock Units, net of shares withheld for taxes	—	—	162,019	—	—	—	(510)	—	—	(510)
Issuance of common stock from exercise of stock options	—	—	78,362	—	—	—	774	—	—	774
Shares purchased through employee stock purchase plan, net of shares withheld for taxes	—	—	38,549	—	—	—	23	—	—	23
Unrealized gain on investments, net	—	—	—	—	—	—	—	68	—	68
Stock-based compensation	—	—	—	—	—	—	13,621	—	—	13,621
Net loss	—	—	—	—	—	—	—	—	(78,259)	(78,259)
Balance, December 31, 2025	2	$ —	18,512,757	$ 18	18,792	$ —	$ 531,485	$ 68	$ (448,522)	$ 83,049

See accompanying notes to the consolidated financial statements.

AVALO THERAPEUTICS, INC. and SUBSIDIARIES

Consolidated Statements of Cash Flows
(Amounts in thousands)

	Year Ended December 31,	
	2025	**2024**
Operating activities		
Net loss	$ (78,259)	$ (35,129)
Adjustments to reconcile net loss used in operating activities:		
Depreciation and amortization	344	169
Stock-based compensation	13,621	5,852
Accretion of available-for-sale investments, net	(690)	—
Change in fair value of derivative liability	9,520	2,930
Acquired in-process research and development	—	27,641
Excess of initial warrant fair value over private placement proceeds	—	79,276
Change in fair value of warrant liability	—	(121,611)
Transaction costs paid pursuant to private placement	—	7,485
Transaction costs paid upon exercise of warrants issued in private placement	—	1,734
Contingent consideration paid pursuant to AlmataBio Transaction	—	(12,500)
Lease early termination fee	—	(309)
Deferred taxes	165	114
Changes in assets and liabilities:		
Other receivables	—	(475)
Prepaid expenses and other assets	(2,588)	(2,871)
Accounts payable	(146)	(163)
Accrued expenses and other liabilities, excluding lease liability	6,662	(1,111)
Lease liability, net	(87)	(88)
Net cash used in operating activities	(51,458)	(49,056)
Investing activities		
Purchase of investments	(113,720)	—
Maturities of investments	32,000	—
Cash assumed from AlmataBio Transaction	—	356
Net cash (used in) provided by investing activities	(81,720)	356
Financing activities		
Proceeds from sale of common stock pursuant to ATM Program	14,762	—
Transaction costs paid pursuant to ATM Program	(462)	—
Proceeds from exercise of stock options	774	—
Proceeds from issuance of common stock under employee stock purchase plan, net of cash paid related to withholding shares to satisfy tax withholding obligations	23	68
Cash paid related to withholding shares to satisfy RSU tax withholding obligations	(510)	—
Proceeds from private placement investment, gross	—	115,625
Transaction costs paid pursuant to private placement	—	(7,485)
Proceeds from exercise of warrants issued in private placement, gross	—	69,375
Transaction costs paid upon exercise of warrants issued in private placement	—	(1,734)
Net cash provided by financing activities	14,587	175,849
(Decrease) increase in cash, cash equivalents, and restricted cash	(118,591)	127,149
Cash, cash equivalents, and restricted cash at beginning of period	134,696	7,547
Cash, cash equivalents, and restricted cash at end of period	$ 16,105	$ 134,696
Supplemental disclosures of non-cash activities		
Issuance of common stock and Series C Preferred Stock pursuant to AlmataBio Transaction	$ —	$ 12,272
Remeasurement of lease	$ —	$ (312)

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

	December 31,	
	2025	2024
Cash and cash equivalents	$ 15,858	$ 134,546
Restricted cash, current	37	19
Restricted cash, non-current	210	131
Total cash, cash equivalents and restricted cash	$ 16,105	$ 134,696

See accompanying notes to the consolidated financial statements.

1. Business

Avalo Therapeutics, Inc. (the "Company" or "Avalo" or "we") is a clinical stage biotechnology company fully dedicated to developing IL-1β-based treatments for immune-mediated inflammatory diseases. Our lead product candidate, abdakibart (AVTX-009), an anti-IL-1β monoclonal antibody ("mAb") is in a Phase 2 clinical trial for hidradenitis suppurativa ("HS"). We are also exploring additional opportunities to make an impact in prevalent indications that have significant remaining unmet needs.

Avalo was incorporated in Delaware and commenced operation in 2011, and completed its initial public offering in October 2015.

Liquidity

Since inception, we have incurred significant operating losses and negative cash flows from our operations. We have primarily funded our operations to date through sales of equity securities, out-licensing transactions and sales of assets.

For the year ended December 31, 2025, Avalo generated a net loss of $78.3 million and negative cash flows from operations of $51.5 million. As of December 31, 2025, Avalo had $98.3 million in cash and cash equivalents and short-term investments.

In accordance with Accounting Standards Codification Topic 205-40, *Presentation of Financial Statements - Going Concern*, the Company evaluated its ability to continue as a going concern within one year after the date that the accompanying consolidated financial statements are issued. Based on our current operating plans, we expect that our existing cash, cash equivalents and short-term investments are sufficient to fund operations for at least twelve months from the filing date of this Annual Report on Form 10-K. The Company closely monitors its cash and cash equivalents and seeks to balance the level of cash and cash equivalents with our projected needs to allow us to withstand periods of uncertainty relative to the availability of funding on favorable terms. We may satisfy any future cash needs through sales of equity securities under the Company's at-the-market program or other equity financings, out-licensing transactions, strategic alliances/collaborations, sale of programs, and/or mergers and acquisitions. There can be no assurance that any financing or business development initiatives can be realized by the Company, or if realized, what the terms may be. To the extent that we raise capital through the sale of equity, the ownership interest of our existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. Further, if the Company raises additional funds through collaborations, strategic alliances or licensing arrangements with third parties, the Company might have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates.

2. Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board (the "FASB"). The consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets, and the satisfaction of liabilities in the ordinary course of business.

In the first quarter of 2025, the Company concluded that it would include other receivables within the prepaid expenses and other current assets line in the Company's consolidated balance sheets and statement of cash flows. The Company reclassified $0.6 million from other receivables to prepaid expenses and other current assets as of December 31, 2024 within the consolidated balance sheets and $0.5 million from other receivables to prepaid expenses and other current assets for the year ended December 31, 2024 within the statement of cash flows, to conform with the current period presentation.

Unless otherwise indicated, all amounts in the following tables are in thousands except share and per share amounts.

Principles of Consolidation

The consolidated financial statements include the accounts of Avalo Therapeutics, Inc. and its wholly-owned subsidiaries after elimination of all intercompany balances and transactions.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosures. On an ongoing basis, management evaluates its estimates, including estimates related to but not limited to, revenue recognition, cost of product sales, stock-based compensation, fair value measurements, the valuation of derivative liabilities, the valuation of warrant liabilities, cash flows used in management's going concern assessment, income taxes, goodwill, and clinical trial accruals. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of 90 days or fewer when purchased to be cash equivalents. These assets include investments in money market funds and U.S. Treasury securities. Cash equivalents are reflected at fair value, as further described in Note 6 - Fair Value Measurements.

Concentration of Credit Risk

The primary financial instruments that subject the Company to concentrated credit risk include cash, cash equivalents, and short-term investments. The Company maintains its cash, cash equivalents, and short-term investments with high-quality financial institutions and, consequently, the Company believes that such funds are subject to minimal credit risk. The Company's cash equivalents consist of money market funds, which are invested in U.S. Treasury and government agency obligations, and the Company's short-term investments consist of U.S. Treasury securities. Credit risk in these securities is reduced as a result of the Company's investment policy to make high credit quality investments with its cash and cash equivalents. The Company's investment policy limits investment instruments to investment-grade securities with the objective to preserve capital and to maintain liquidity until the funds can be used in business operations.

Investments

The Company generally invests its excess cash in money market funds and marketable debt securities. Such investments are included in either cash and cash equivalents (if the original maturity, from the date of purchase, is 90 days or fewer) or short-term investments (if the original maturity, from the date of purchase, is in excess of 90 days and less than 1 year) on the consolidated balance sheet, as they represent the investment of funds readily convertible to cash to fund current operations. The Company classifies its investments as either trading, held-to-maturity or available-for-sale based on facts and circumstances present at the time it purchases the securities. As of December 31, 2025, all of our investments were classified as available-for-sale, which are reported at fair value at each balance sheet date, and for which fair value measurement data is obtained from independent pricing services. For securities with unrealized holding gains and losses (the adjustments to fair value), when the Company expects to receive cash flows sufficient to recover the amortized cost basis of a security, such gains and losses are included in "Accumulated other comprehensive income" as a component of stockholders' equity. The Company identifies credit losses when it does not expect to receive cash flows sufficient to recover the amortized cost basis of a security. On a quarterly basis, the Company evaluates whether decreases in the fair values of its investments are below their amortized cost, and if so, it marks the investment to market through a charge to our consolidated statements of operations and comprehensive loss. Realized gains and losses, if any, are included in interest income, net on the consolidated statements of operations and comprehensive loss. The amortized costs of investments are adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income, net on the consolidated statements of operations and comprehensive loss.

Restricted Cash

Restricted cash consists of the 2016 Amended and Restated Employee Stock Purchase Plan (the "ESPP") deposits, credit card deposits, and security deposits for our leased corporate offices.

Derivative Liability

Upon entering into a transaction to sell the Company's future rights to milestones and royalty payments of previously out-licensed assets, the Company must assess whether the transaction is a derivative under ASC 815, *Derivatives and Hedging*. The requirements for the sale to be treated as a derivative are as follows: a) one or more underlying; b) one or more notional amounts or payment provisions or both; c) no initial net investment or an initial net investment that is smaller than would be required for other types of contracts that would be expected to have a similar response to changes in market factors; and d) net settlement provisions.

If the transaction meets the requirements to be treated as a derivative, we estimate the fair value of the derivative liability on the date of issuance. The derivative liability is re-valued each reporting period and any change in the fair value is recorded as a gain or loss in the statements of operations and comprehensive loss.

Warrant Liability

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480, *Distinguishing Liabilities from Equity* and ASC 815, *Derivatives and Hedging*. Warrants classified as equity are recorded at fair value as of the date of issuance on the Company's consolidated balance sheets and no further adjustments to their valuation are made. Warrants classified as derivative liabilities that require separate accounting as liabilities are recorded on the Company's consolidated balance sheets at their fair value on the date of issuance and are re-valued on each subsequent balance sheet date until such instruments are exercised or expire, with any changes in the fair value between reporting periods recorded on the consolidated statement of operations and comprehensive loss. The assessment of whether the warrants are accounted for as equity-classified or liability-classified instruments is re-evaluated on a periodic basis.

Leases

The Company determines if an arrangement is a lease at inception. If an arrangement contains a lease, the Company performs a lease classification test to determine if the lease is an operating lease or a finance lease. The Company has identified one operating lease, which serves as administrative office space. Right-of-use ("ROU") assets represent the right to use an underlying asset for the lesser of the lease term and useful life and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease liabilities are recognized on the commencement date of the lease based on the present value of the future lease payments over the lease term and are included in other long-term liabilities and other current liabilities on the Company's consolidated balance sheet. ROU assets are valued at the initial measurement of the lease liability, plus any indirect costs or rent prepayments, and reduced by any lease incentives and any deferred lease payments. Operating ROU assets are recorded in property and equipment, net on the consolidated balance sheets and are amortized over the lesser of the lease term and useful life. To determine the present value of lease payments on lease commencement, the Company uses the implicit rate when readily determinable, however, as most leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on information available at commencement date. Our operating lease agreements may include options to extend the lease term or terminate it early. We include options to extend or terminate leases in the ROU operating lease asset and liability when it is reasonably certain we will exercise these options. If an original lease contract is terminated early, but the lessee retains exclusive use of the space for a period after the termination option is exercised, the lease is treated as a reduction of the lease term rather than a lease termination. Furthermore, the Company has elected the practical expedient to account for the lease and non-lease components in a single lease component for the leased property asset class. Lease expense is recognized on a straight-line basis over the life of the lease and is included within general and administrative expenses.

Property and Equipment

Property and equipment consists of computers, office equipment, furniture, ROU assets (discussed above), and leasehold improvements and is recorded at cost. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed to operations as incurred. Property and equipment are depreciated on a straight-line basis over their estimated useful lives. The Company uses a life of four years for computers and software, and five years for equipment and furniture. For leasehold improvements, depreciation of the asset will begin at the date it is placed in service and the depreciable life of the leasehold improvement is the shorter of the lease term or the improvement's useful life. Upon retirement or sale, the cost of the disposed asset and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is recognized. Property and equipment are reviewed for impairment as events or changes in circumstances occur indicating that the carrying value of the asset may not be recoverable. If an impairment is deemed to exist, the loss would be calculated based on the excess of the asset's carrying value over its estimated fair value.

Asset Acquisitions

The Company evaluates acquisitions of assets and other similar transactions to assess whether the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen test is met, the transaction is accounted for as an asset acquisition. If the screen test is not met, further determination is required as to whether the Company has acquired inputs and processes that have the ability to create outputs which would meet the definition of a business. Significant judgment is required in the application of the screen test to determine whether an acquisition is a business combination or an acquisition of assets.

Business Combinations

For acquisitions that meet the definition of a business under ASC 805, *Business Combinations* ("ASC 805"), the Company records the acquisition using the acquisition method of accounting. All of the assets acquired, liabilities assumed, contractual contingencies, and contingent consideration, when applicable, are recorded at fair value at the acquisition date. Any excess of the purchase price over the fair value of the net assets acquired is recorded as goodwill. The application of the acquisition method of accounting requires management to make significant estimates and assumptions in the determination of the fair value of assets acquired and liabilities assumed in order to properly allocate purchase price consideration. For acquisitions that do not meet the definition of a business under ASC 805, the Company accounts for the transaction as an asset acquisition.

Segment Information

Operating segments are identified as components of an enterprise for which separate discrete financial information is available for evaluation by the chief operating decision maker ("CODM"), or decision-making group, in making decisions on how to allocate resources and assess performance. As of December 31, 2025, the Company's CODM was its Chief Executive Officer. The Chief Executive Officer views the Company's operations and manages the business as one operating segment. All long-lived assets of the Company reside in the United States.

Goodwill

The Company's goodwill relates to historical acquisitions that were accounted for as business combinations and represents the excess of the purchase price over the fair value of the net assets acquired when accounted for using the acquisition method of accounting. In accordance with ASC 350, *Intangibles - Goodwill and Other*, goodwill is not amortized but is evaluated for impairment on an annual basis or more frequently if an event occurs or circumstances change that would more-likely-than-not reduce the fair value of the Company's reporting unit below its carrying amount. A reporting unit is an operating segment or one level below the operating segment. As standalone discrete and detailed financial information is not available or regularly reviewed below the company-wide level, the Company consists of one reporting unit.

Upon disposal of a portion of a reporting unit that constitutes a business, the Company assigns goodwill based on the relative fair values of the portion of the reporting unit being disposed and the portion of the reporting unit remaining. This approach requires a determination of the fair value of both the business to be disposed of and the business (or businesses) within the reporting unit that will be retained.

Product Revenues, net

The Company historically generated its revenue from sales of its prescription drug to its customers. The license and supply agreement for the Millipred® product ended, as expected, on September 30, 2023, therefore the Company does not expect future gross product revenues until the potential commercialization of its pipeline product candidates. The Company had identified a single product delivery performance obligation, which was the provision of prescription drugs to its customers based upon master service agreements in place with wholesaler distributors. The performance obligation was satisfied at a point in time, when control of the product had been transferred to the customer, which was the time the product had been received by the customer. The Company determined the transaction price based on fixed consideration in its contractual agreements and the transaction price was allocated entirely to the performance obligation to provide the prescription drug.

Revenues from sales of products were recorded net of any variable consideration for estimated allowances for returns, chargebacks, distributor fees, prompt payment discounts, government rebates, and other common gross-to-net revenue adjustments. The identified variable consideration was recorded as a reduction of revenue at the time revenues from product sales were recognized. The Company recognized revenue only to the extent that it was probable that a significant revenue reversal would not occur in a future period.

Provisions for returns and government rebates were included within current liabilities in the consolidated balance sheet. Provisions for prompt payment discounts and distributor fees were included as a reduction to accounts receivable. Calculating these items involves estimates and judgments based on sales or invoice data, contractual terms, historical utilization rates, new information regarding changes in these programs' regulations and guidelines that would impact the amount of the actual rebates, Company expectations regarding future utilization rates for these programs, and channel inventory data. These estimates may differ from actual consideration amount received and the Company re-assesses these estimates and judgments each reporting period to adjust accordingly.

Returns and Allowances

The license and supply agreement for the Millipred® product expired, as expected, on September 30, 2023. Consistent with industry practice, for its Millipred® product, the Company maintains a return policy that allows customers to return product within a specified period both prior to and, in certain cases, subsequent to the product's expiration date. The Company's return policy for sales made prior to August 31, 2021, generally allows for customers to receive credit for expired products within six months prior to expiration and within one year after expiration. The Company's return policy for sales subsequent to August 31, 2021, generally allows for customers to receive credit for expired products within thirty days prior to expiration and within ninety days after expiration, however, certain customers have an extended policy which allows them to receive credit for expired products within six months prior to expiration and within one year after expiration. Based on these policies, product returns were accepted through September of 2025, however, could be received by the Company later depending on timing of receipt and communication by its third-party logistics provider.

The provision for returns and allowances consists of estimates for future product returns and pricing adjustments. The primary factors considered in estimating potential product returns include:

- the shelf life or expiration date of each product;
- historical levels of expired product returns;
- external data with respect to inventory levels in the wholesale distribution channel;
- external data with respect to prescription demand for each of the Company's products; and
- the estimated returns liability to be processed by year of sale based on analysis of lot information related to actual historical returns.

License and Other Revenue

The Company recognizes revenues from collaboration, license or other research or sale arrangements when or as performance obligations are satisfied. For milestone payments, the Company assesses, at contract inception, whether the milestones are considered probable of being achieved. If it is probable that a significant revenue reversal will occur, the Company will not record revenue until the uncertainty has been resolved. Milestone payments that are contingent upon regulatory approval are not considered probable until the approvals are obtained as it is outside of the control of the Company. If it is probable that significant revenue reversal will not occur, the Company will estimate the milestone payments using the most likely amount method. The Company reassesses the milestones each reporting period to determine the probability of achievement.

Cost of Product Sales

Cost of product sales is comprised of (i) costs to acquire products sold to customers, (ii) royalty payments the Company is required to pay based on the product's net profit pursuant to its license and supply agreement, (iii) the value of any write-offs of obsolete or damaged inventory that cannot be sold and (iv) the write-off of receivables that are deemed not probable to be collected, or vice versa. The license and supply agreement for the Millipred® product expired, as expected, on September 30, 2023.

Research and Development Costs

Research and development costs are expensed as incurred. These costs include, but are not limited to, expenses incurred under agreements with contract research organizations and investigative sites that conduct clinical trials and preclinical studies; the cost of acquiring, developing and manufacturing clinical trial materials; costs associated with preclinical activities and regulatory operations, pharmacovigilance and quality; costs and milestones associated with certain licensing agreements, and employee-related expenses, including salaries, benefits and stock-based compensation of research and development personnel.

Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to the Company by its vendors, such as clinical research organizations, with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development expense, as the case may be.

The Company is a party to license and development agreements for in-licensed research and development assets with third parties. Such agreements often contain future payment obligations such as royalties and milestone payments. The Company recognizes a liability (and related research and development expense) for each milestone if and when such milestone is probable and can be reasonably estimated.

As typical in the biotechnology industry, each milestone has its own unique risks that the Company evaluates when determining the probability of achieving each milestone and the probability of success evolves over time as the programs progress and additional information is obtained. The Company considers numerous factors when evaluating whether a given milestone is probable including (but not limited to) the regulatory pathway, development plan, ability to dedicate sufficient funding to reach a given milestone and the probability of success.

Clinical Trial Expense Accruals

The Company estimates its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. The Company's objective is to reflect the appropriate trial expenses in its financial statements by matching those expenses with the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the progress of the trial as measured by subject progression and the timing of various aspects of the trial. The Company determines accrual estimates by taking into account discussions with applicable personnel and outside service providers as to the progress or state of consummation of trials, or the services completed. During the course of a clinical trial, the Company adjusts its clinical expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. The Company's clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed might vary and might result in it reporting amounts that are too high or too low for any particular period.

Acquired In-Process Research and Development Expenses

Acquired in-process research and development ("IPR&D") expense includes the initial costs of IPR&D projects, acquired directly in a transaction other than a business combination, that do not have an alternative future use. Refer to the Asset Acquisitions accounting policy above for additional information regarding the considerations for evaluating acquisitions and other similar transactions to assess whether the transaction should be accounted for as a business combination or an asset acquisition.

Stock-Based Compensation

The Company applies the provisions of ASC 718, *Compensation—Stock Compensation*, which requires the measurement and recognition of compensation expense for all stock-based awards made to employees, including but not limited to employee stock options and restricted stock units, in the statements of operations and comprehensive loss.

For stock options issued to employees and members of the board of directors for their services, the Company estimates the grant date fair value of each option using the Black-Scholes option pricing model. The use of the Black-Scholes option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected term of the option, risk-free interest rates and expected dividend yields of the common stock. Additionally, the stock price on the date of grant is utilized in the Black-Scholes option pricing model. For awards subject to service-based vesting conditions, including those with a graded vesting schedule, the Company recognizes stock-based compensation expense equal to the grant date fair value of stock options on a straight-line basis over the requisite service period, which is generally the vesting term. Forfeitures are recorded as they are incurred.

Each Restricted Stock Unit ("RSU") represents one equivalent share of our common stock to be issued after satisfying the applicable continued service-based vesting criteria over a specified period. The fair value of these RSUs is based on the closing price of our common stock on the date of the grant. The compensation for RSUs is recognized on a straight-line basis over the vesting period.

Each Performance Stock Unit ("PSU") represents one equivalent share of our common stock to be issued after achievement of the performance goals specified in the grant. The Company estimates the fair value of our PSUs as of the grant date based upon the expected likelihood of achievement of the performance goals specified in the grant and the closing market price of our common stock on the date of grant. The Company recognizes stock-based compensation expense over the requisite service period, if it is probable that the performance goal will be achieved.

These estimates involve inherent uncertainties and the application of management's judgment. If factors change and different assumptions are used, the Company's stock-based compensation expense could be materially different in the future.

Income Taxes

The Company accounts for income taxes under the asset and liability method in accordance with ASC 740, *Income Taxes* ("ASC 740"). Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Deferred tax assets primarily include net operating loss ("NOL") and tax credit carryforwards, accrued expenses not currently deductible and the cumulative temporary differences related to certain research and patent costs. Certain tax attributes, including NOLs and research and development credit carryforwards, may be subject to an annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "IRC"). See Note 13 for further information. The portion of any deferred tax asset for which it is more likely than not that a tax benefit will not be realized must then be offset by recording a valuation allowance. The Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not to be sustained upon examination based on the technical merits of the position. The amount for which an exposure exists is measured as the largest amount of benefit determined on a cumulative probability basis that the Company believes is more likely than not to be realized upon ultimate settlement of the position. The Company's policy is to record interest and penalties on uncertain tax positions as income tax expense. As of December 31, 2025, the Company did not believe any material uncertain tax positions were present.

Comprehensive Loss

Comprehensive loss comprises net loss and net change in stockholders' equity during a period from sources other than transactions with stockholders. For the years ended December 31, 2025, our comprehensive loss is comprised of net loss and unrealized gains on investments. For the year ended December 31, 2024, the Company's net loss was equal to comprehensive loss.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures," which requires disclosure of specific categories in the rate reconciliation, including additional information for reconciling items that meet a quantitative threshold, and specific disaggregation of income taxes paid and tax expense. The amendment is effective for fiscal years beginning after December 15, 2024. The Company has adopted ASU 2023-09 using a retrospective approach on its annual consolidated financial statements in the current period.

Recently Issued Accounting Pronouncements Not Yet Adopted

In September 2025, the FASB issued ASU 2025-07, Derivatives and Hedging (Topic 815) and Revenue from Contracts with Customers (Topics 606): Derivatives Scope Refinements and Scope Clarification for Share-based Noncash Consideration from a Customer in a Revenue Contract ("ASU 2025-07"), which, among other items, amends the application of derivative accounting to contracts with features based on the operations or activities of one of the parties to the contract. The amendments are expected to (a) reduce the cost and complexity of evaluating whether contracts with features based on the operations or activities of one of the parties to the contract are derivatives, (b) better portray the economics of those contracts in the financial statements, and (c) reduce diversity in practice resulting from the broad application of the current guidance and changing business environment. The standard is effective for fiscal years beginning after December 15, 2026, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2025-07.

In November 2024, the FASB issued ASU 2024-03, Disaggregation of Income Statement Expenses, which requires disaggregation and disclosure of specified information about certain costs and expenses in the notes to the financial statements. The standard is effective for fiscal years beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2024-03.

3. Asset Acquisition

AlmataBio Transaction

On March 27, 2024, the Company acquired abdakibart (AVTX-009), an anti-IL-1β mAb, through a merger of AlmataBio, Inc. ("AlmataBio") with and into its wholly owned subsidiary (the "AlmataBio Transaction"). The Company's acquisition of AlmataBio was structured as a stock-for-stock transaction whereby all outstanding equity interests in AlmataBio were exchanged in a merger for a combination of the Company's common stock and shares of the Company's non-voting convertible preferred stock (the "Series C Preferred Stock"), resulting in the issuance of 171,605 shares of Company common stock and 2,412 shares of Series C Preferred Stock. Upon Company stockholder approval on August 13, 2024 and subject to beneficial ownership limitations, 2,063 shares of Series C Preferred Stock issued to former AlmataBio stockholders automatically converted into 2,062,930 shares of common stock.

In addition to the shares issued, a cash payment of $7.5 million was due to the former AlmataBio stockholders upon the closing of a private placement. The private placement closed on March 28, 2024 and the Company paid the $7.5 million in April 2024. The Company is also required to pay potential development milestone payments to the former AlmataBio stockholders, including $5.0 million due upon the first patient dosed in a Phase 2 trial in patients with hidradenitis suppurativa ("HS") for abdakibart (AVTX-009), and $15.0 million due upon the first patient dosed in a Phase 3 trial for abdakibart (AVTX-009), both of which are payable in cash or Avalo stock at the election of the former AlmataBio stockholders, subject to the terms and conditions of the definitive merger agreement. In October 2024, the first development milestone was met and the Company paid the $5.0 million cash payment.

The Company was the acquiring company for accounting purposes. In connection with the AlmataBio Transaction, substantially all of the consideration paid is allocable to the fair value of acquired in-process research and development ("IPR&D"), specifically abdakibart (AVTX-009), and as such the acquisition is treated as an asset acquisition. The Company initially recognized AlmataBio's assets and liabilities by allocating the accumulated cost of the acquisition based on their relative fair values, as estimated by management. The net assets acquired as of the transaction date have been combined with the assets, liabilities, and results of operations of the Company on consummation of the AlmataBio Transaction. In accordance with ASC 730, *Research and Development*, the portion of the consideration allocated to the acquired IPR&D, specifically abdakibart (AVTX-009), based on its relative fair value, is included as an operating expense as there is no alternative future use.

Below is a summary of the total consideration, assets acquired and the liabilities assumed in connection with the AlmataBio Transaction (in thousands):

	Year Ended December 31, 2024
Stock consideration[1]	$ 12,272
Milestone payment due upon close of private placement investment[2]	7,500
Milestone payment due upon first patient dosed in a Phase 2 trial[2]	5,000
Transaction costs	2,402
Total GAAP Purchase Price at Close	**$ 27,174**
Acquired IPR&D	$ 27,641
Cash	356
Accrued expenses and other current liabilities	(823)
Total net assets acquired and liabilities assumed	**$ 27,174**

[1] Equal to the aggregate shares of common stock issued of 171,605 and the aggregate shares of Series C Preferred Stock issued of 2,412 (as-convertible to 2,412,000 shares of common stock), multiplied by the Company's closing stock price of $4.75 on March 27, 2024. On August 13, 2024 upon Company stockholder approval and subject to beneficial ownership limitations, 2,063 *of the 2,412 shares of Series C Preferred Stock were converted into* 2,062,930 *shares of common stock.*

[2] Avalo deemed these milestones probable and estimable as of the transaction close date and therefore included them as part of the GAAP purchase price at close. The milestone payment due upon the close of the private placement was paid in April 2024. The milestone payment due upon the first patient dosed in a Phase 2 trial was paid in October 2024.

The cost to acquire the IPR&D asset related to abdakibart (AVTX-009) was expensed on the date of the AlmataBio Transaction as it was determined to have no future alternative use. Accordingly, costs associated with the AlmataBio Transaction to acquire the asset were expensed as incurred in acquired IPR&D.

4. Revenue

The Company's license and supply agreement for Millipred®, an oral prednisolone indicated across a wide variety of inflammatory conditions, expired, as planned, on September 30, 2023. Avalo considered Millipred® a non-core asset. Historically, the Company sold Millipred® in the United States primarily through wholesale distributors, who accounted for substantially all of the Company's net product revenues and trade receivables. The Company continues to monitor estimates for commercial liabilities for Millipred®, such as sales returns. As additional information becomes available, the Company could recognize expense (or a benefit) for differences between actuals or updated estimates to the reserves previously recognized.

Pursuant to the Millipred® license and supply agreement, Avalo was required to pay the supplier fifty percent of the net profit of the Millipred® product following each calendar quarter, with a $0.5 million quarterly minimum payment contingent on Avalo achieving certain net profit thresholds as stipulated in the agreement. The profit share commenced on July 1, 2021 and ended on September 30, 2023. Within twenty-five months of September 30, 2023, the net profit share is subject to a reconciliation process, where estimated deductions to arrive at net profit will be reconciled to actuals, which might result in Avalo owing additional amounts to the supplier or vice versa, which would be recognized in cost of product sales.

There was no gross revenue recognized from sales for the years ended December 31, 2025 and December 31, 2024. The Company recognized minimal and $0.4 million of net product revenue for the year ended December 31, 2025 and December 31, 2024, respectively, both related to adjustments in gross-to-net estimates, as noted above.

5. Net Loss Per Share

The Company had two classes of stock outstanding during the year ended December 31, 2025 and December 31, 2024, common stock and preferred stock. The Company computes net loss per share using the two-class method, as the Series C Preferred Stock participates in distributions with the Company's common stock. The two-class method of computing net loss per share is an earnings allocation formula that determines net loss for common stock and any participating securities according to dividends declared and participation rights in undistributed earnings. As the Company is in a net loss position for the year ended December 31, 2025 and December 31, 2024, the two-class method of calculating net loss per share results in no allocation of undistributed losses to participating securities.

Basic net loss per share for common stock is computed by dividing the sum of distributed and undistributed earnings by the weighted average number of shares outstanding for the period.

Diluted net loss per share includes the potential dilutive effect of common stock equivalents as if such securities were converted or exercised during the period, when the effect is dilutive. Common stock equivalents include: (i) outstanding stock options and restricted stock units, which are included under the "treasury stock method" when dilutive; and (ii) common stock to be issued upon the exercise of outstanding warrants, which are included under the "treasury stock method" when dilutive, and (iii) preferred stock under the if-converted method. While the impact of these items is generally anti-dilutive during periods of net loss, the Company will determine whether the common stock equivalents should be included in diluted loss per share pursuant to sequencing rules.

The following tables set forth the computation of basic and diluted net loss per share of common stock for the years ended December 31, 2025 and December 31, 2024 (in thousands, except per share amounts):

	Year Ended December 31, 2025	
	Common stock	
Net loss	$	(78,259)
Weighted average shares		13,404,830
Basic and diluted net loss per share	$	(5.84)

	Year Ended December 31, 2024 Common stock
Basic loss per share:	
Net loss	$ (35,129)
Weighted average shares	4,426,149
Basic net loss per share	$ (7.94)
Diluted loss per share:	
Numerator:	
Net loss - basic	$ (35,129)
Change in fair value of warrant liability	(121,611)
Net loss - diluted	$ (156,740)
Denominator:	
Effect of dilutive securities:	
Weighted average shares - basic	4,426,149
Common shares issuable for warrants	$ 3,070,240
Weighted average shares - diluted	7,496,389
Diluted net loss per share	$ (20.91)

The following outstanding securities have been excluded from the computation of diluted weighted shares outstanding for the years ended December 31, 2025 and 2024, as they could have been anti-dilutive:

	December 31,	
	2025[2]	**2024[2]**
Stock options	4,591,257	1,999,749
Warrants on common stock	148	148
Series C Preferred Stock (as-convertible to common stock)[1]	18,792,360	24,895,920
Restricted Stock Units	387,064	632,100
Performance Stock Units[3]	492,500	—

[1] Each share of the Company's Series C Preferred Stock is convertible to 1,000 shares of common stock, subject to certain beneficial ownership limitations.

[2] Pursuant to the AlmataBio Transaction, the Company is required to pay potential development milestone payments to the former AlmataBio stockholders in cash or Avalo stock at the election of the former AlmataBio stockholders; refer to Notes 3 and 14 for more information. In the event of share settlement, the number of Avalo shares delivered will vary based on the Company's stock price. These additional shares are not included in the computation of basic and diluted net loss per share for the year ended December 31, 2025 or 2024 pursuant to the guidance on contingently issuable shares.

[3] Calculated assuming 100% achievement of performance metric.

Subsequent to December 31, 2025, an aggregate of approximately 4,542 shares of Series C Preferred Stock were converted to 4,542,396 shares of common stock.

6. Fair Value Measurements

ASC 820, *Fair Value Measurements and Disclosures* ("ASC 820") defines fair value as the price that would be received to sell an asset, or paid to transfer a liability, in the principal or most advantageous market in an orderly transaction between market participants on the measurement date. The fair value standard also establishes a three-level hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The valuation hierarchy is based upon the transparency of inputs to the valuation of an asset or liability on the measurement date.

The three levels are defined as follows:

- Level 1—inputs to the valuation methodology are quoted prices (unadjusted) for an identical asset or liability in an active market.
- Level 2—inputs to the valuation methodology include quoted prices for a similar asset or liability in an active market or model-derived valuations in which all significant inputs are observable for substantially the full term of the asset or liability.
- Level 3—inputs to the valuation methodology are unobservable and significant to the fair value measurement of the asset or liability.

The Company measures the fair value of money market funds based on quoted prices in active markets for identical securities. Investments also include U.S. Treasury securities, which are valued either based on recent trades of securities in inactive markets or based on quoted market prices of similar instruments and other significant inputs derived from, or corroborated by, observable market data.

The following table presents, for each of the fair value hierarchy levels required under ASC 820, the Company's assets and liabilities that are measured at fair value on a recurring basis (in thousands):

	December 31, 2025			
	Fair Value Measurements Using			
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets				
Cash equivalents:				
Money market funds	$ 9,069	$ —	$ —	$ 9,069
Marketable debt securities:				
U.S. Treasury securities	—	82,478	—	82,478
Total financial assets	$ 9,069	82478000	$ —	$ 91,547
Liabilities				
Derivative liability	$ —	$ —	$ 18,000	$ 18,000

	December 31, 2024			
	Fair Value Measurements Using			
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets				
Cash equivalents				
Money market funds	$ 133,148	$ —	$ —	$ 133,148
Total financial assets	$ 133,148	$ —	$ —	$ 133,148
Liabilities				
Derivative liability	$ —	$ —	$ 8,480	$ 8,480

The carrying amounts reported in the accompanying financial statements for cash, restricted cash, prepaid and other current assets, accounts payable, and accrued expenses and other current liabilities approximate their respective fair values because of the short-term nature of these accounts.

Level 3 Valuation

The table presented below is a summary of changes in the fair value of the Company's Level 3 valuations for the warrant liability and derivative liability for the years ended December 31, 2025 and 2024:

	Derivative liability	Total
Balance at December 31, 2024	$ 8,480	$ 8,480
Change in fair value	9,520	9,520
Balance at December 31, 2025	$ 18,000	$ 18,000

	Warrant liability	Derivative liability	Total
Balance at December 31, 2023	$ —	$ 5,550	$ 5,550
Initial valuation of warrant liability	194,901	—	194,901
Change in fair value	(121,611)	2,930	(118,681)
Settlement of warrant liability	(73,290)	—	(73,290)
Balance at December 31, 2024	$ —	$ 8,480	$ 8,480

Derivative Liability

In the fourth quarter of 2022, Avalo sold its economic rights to future milestone and royalty payments for previously out-licensed assets AVTX-501, AVTX-007, and AVTX-611 to ES Therapeutics, LLC ("ES"), an affiliate of Armistice Capital LLC ("Armistice"), in exchange for $5.0 million (the "ES Transaction"). At the time of the transaction, Armistice was a significant stockholder of the Company whose chief investment officer, Steven Boyd, and managing director, Keith Maher, served on Avalo's Board until August 8, 2022. The ES Transaction was approved in accordance with Avalo's related party transaction policy.

The economic rights sold include (a) rights to a milestone payment of $20.0 million upon the filing and acceptance of an NDA for AVTX-501 pursuant to an agreement with Janssen Pharmaceutics, Inc., now Johnson & Johnson Innovative Medicine ("J&J") (the "AVTX-501 Milestone") and (b) rights to any future milestone payments and royalties relating to AVTX-007 under a license agreement with Apollo AP43 Limited ("Apollo"), including up to $6.25 million of development milestones, up to $67.5 million in sales-based milestones, and royalty payments over a ten year period of a low single digit percentage of annual net sales (which percentage increases to another low single digit percentage if annual net sales exceed a specified threshold) (the "AVTX-007 Milestones and Royalties"). In addition, Avalo waived all its rights to AVTX-611 sales-based payments of up to $20.0 million that were payable by ES.

The exchange of the economic rights of the AVTX-501 Milestone and AVTX-007 Milestones and Royalties for cash met the definition of a derivative instrument. The fair value of the derivative liability is determined using a combination of a scenario-based method and an option pricing method (implemented using a Monte Carlo simulation). The significant inputs including probabilities of success, expected timing, and forecasted sales as well as market-based inputs for volatility, risk-adjusted discount rates and allowance for counterparty credit risk are unobservable and based on the best information available to Avalo. Certain information used in the valuation is inherently limited in nature and could differ from J&J's and Apollo's internal estimates.

The fair value of the derivative liability as of the transaction date was approximately $4.8 million, of which $3.5 million was attributable to the AVTX-501 Milestone and $1.3 million was attributable to the AVTX-007 Milestones and Royalties. Subsequent to the transaction date, at each reporting period, the derivative liability is remeasured at fair value. As of December 31, 2025, the fair value of the derivative liability was $18.0 million, all of which was attributable to the AVTX-007 Milestone and Royalties and was classified as a non-current liability. For the year ended December 31, 2025, the $9.5 million change in fair value was recognized in other expense (income), net in the accompanying consolidated statements of operations and comprehensive loss.

The fair value of the AVTX-501 Milestone was deemed to be de minimis, driven by less than 1% probability of success based on Avalo's interpretation of an announcement from J&J in March 2025, noting the discontinuation of the aticaprant depression program (previously referred to as AVTX-501 by Avalo), which was the only indication publicly disclosed, paired with a lack of commitment to an alternative indication. The fair value of AVTX-007 Milestones and Royalties was primarily driven by sales forecasts with peak annual net sales reaching $1.7 billion in atopic dermatitis, an approximate 41% probability of success, and an estimated time to commercialization of approximately 6.5 years, based on Avalo's interpretation of Apollo's September 2025 announcement that the drug met the primary endpoint in its Phase 2a clinical trial in atopic dermatitis. We estimated these unobservable inputs based on limited publicly available information and therefore could differ from J&J's and Apollo's respective internal development plans, assessments of probability of success and other inputs of our fair value calculation. Any changes to these inputs may result in significant changes to the fair value measurement. Notably, the peak annual net sales forecast (for the AVTX-007 Milestones and Royalties) and the probability of success (for both the AVTX-501 Milestone and the AVTX-007 Milestone and Royalties) are the largest drivers of the fair value, so changes to either would likely result in significant changes to their respective fair values.

In the event that J&J and/or Apollo are required to make payment(s) to ES Therapeutics pursuant to the underlying agreements, Avalo will recognize revenue under its existing contracts with those customers for that amount when it is no longer probable there would be a significant revenue reversal with any differences between the fair value of the derivative liability related to that payment immediately prior to the revenue recognition and revenue recognized to be recorded as other expense. However, given Avalo is no longer entitled to collect these payments, the potential ultimate settlement of the payments in the future from J&J and/or Apollo to ES Therapeutics (and the future mark-to-market activity each reporting period) will not impact Avalo's future cash flows.

Warrant Liability

In March 2024, the Company closed a private placement investment with institutional investors in which the investors received shares of Series C Preferred Stock and warrants to purchase shares of Avalo's common stock (or a number of shares of Series C Preferred Stock). Refer to Note 11 - Capital Structure and sub-header "March 2024 Financing" for more information.

The Company determined that the warrants did not satisfy the conditions to be accounted for as equity instruments. As the warrants did not meet the equity contract scope exception, the Company classified the warrants as a derivative liability upon issuance.

The Company's warrant liability was measured at fair value on the issuance date and was measured at fair value each reporting period thereafter until the warrants were fully exercised in the fourth quarter of 2024. As of December 31, 2025 and December 31, 2024, there were no warrants associated with the private placement outstanding and thus no corresponding warrant liability.

For the initial warrant valuation in the first quarter of 2024 and subsequent fair value measurement at each reporting period prior to exercises, the Company utilized the Black-Scholes option pricing model to measure fair value of the warrants, which required assumptions that were subjective and required judgment. As such, the warrant liability was classified as a Level 3 instrument as its value was based on unobservable market inputs. The initial fair value measurement of the warrant liability was $194.9 million and exceeded the initial gross proceeds received from the private placement of $115.6 million, resulting in a $79.3 million loss at issuance of the excess of initial liability fair value. The warrants were fully exercised in the fourth quarter of 2024. Refer to Note 11 - Capital Structure for additional discussion regarding the issuance of the Series C Preferred Stock and common stock pursuant to the warrant exercises.

No other changes in valuation techniques or inputs occurred during the years ended December 31, 2025 and 2024. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the years ended December 31, 2025 and 2024.

7. Investments

The following table summarizes our investments as of December 31, 2025 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	$ 9,069	$ —	$ —	$ 9,069
U.S. Treasury securities	82,410	74	(6)	82,478
Total	$ 91,479	$ 74	$ (6)	$ 91,547

The fair values of our investments by classification in the consolidated balance sheets were as follows:

	As of	
	December 31, 2025	December 31, 2024
Cash and cash equivalents	$ 9,069	$ —
Short-term investments	82,478	—
Total	$ 91,547	$ —

As of December 31, 2025, the aggregate fair value of securities that were in an unrealized loss position for fewer than twelve months was $17.7 million and no investments had been in a continuous unrealized loss position for longer than twelve months. The Company considers any losses to be temporary in nature and the Company has the intent and ability to hold its marketable debt securities until recovery. As a result, the Company determined it did not hold any investments with a credit loss at December 31, 2025.

As of December 31, 2025, accrued interest receivable on available-for-sale investments was $0.7 million, which was included within prepaid expenses and other current assets on our consolidated balance sheets.

8. Property and Equipment and Leases

Property and equipment as of December 31, 2025 and 2024 consisted of the following (in thousands):

	December 31,	
	2025	2024
Furniture and equipment	$ 104	$ 248
Computers and software	34	34
Right-of-use assets	336	741
Leasehold improvements	239	896
Total property and equipment	713	1,919
Less accumulated depreciation	(253)	(710)
Property and equipment, net	$ 460	$ 1,209

Depreciation expense was $0.3 million and $0.2 million for the year ended December 31, 2025 and 2024, respectively.

Leases

Avalo leases its main administrative office space located in Wayne (Chesterbrook), Pennsylvania, which is classified as an operating lease. The initial annual base rent for this office is $0.2 million and the annual operating expenses are approximately $0.1 million. The annual base rent is subject to periodic increases of approximately 2.4% over the term of the lease. The lease has an initial term of 5.25 years from the lease commencement on December 1, 2021 and expires on February 28, 2027.

Additionally, Avalo had an operating lease for administrative office space in Rockville, Maryland, which the Company elected to early-terminate effective January 31, 2026 by providing notice and paying the $0.3 million contractual early termination fee in the fourth quarter of 2024, resulting in a remeasurement and reduction of the lease liability and right-of-use ("ROU") asset by $0.3 million. Because the Company had vacated the property, the ROU asset related to the property had been fully amortized as of December 31, 2025. The lease liability and lease payments related to the property continued through the early-termination date of January 31, 2026. The annual base rent for this office was $0.2 million and was subject to annual 2.5% increases over the term of the lease. The lease provided for a rent abatement for a period of 12 months following the Company's date of occupancy. The lease had an initial term of 10 years from the date the Company made its first annual fixed rent payment, which occurred in January 2020.

The weighted average remaining term of the operating leases at December 31, 2025 was 1.1 years.

Supplemental balance sheet information related to the leased properties include (in thousands):

	As of December 31,	
	2025	2024
Right-of-use assets	$ 336	$ 741
Accrued expenses and other current liabilities	$ 392	$ 568
Other long-term liabilities	35	350
Total operating lease liabilities	$ 427	$ 918

The operating lease right-of-use assets are included in property and equipment and the lease liabilities are included in accrued expenses and other current liabilities and other long-term liabilities in the Company's consolidated balance sheets. The Company utilized a weighted average discount rate of 10.3% to determine the present value of the lease payments.

The components of lease expense for the years ended December 31, 2025 and 2024 were as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Operating lease cost*	$ 477	$ 456

**Includes short-term leases, which are immaterial.*

The following table shows a maturity analysis of the operating lease liability as of December 31, 2025 (in thousands):

	Undiscounted Cash Flows
2026	392
2027	63
Total lease payments	$ 455
Less implied interest	(28)
Total	$ 427

9. Goodwill

The carrying amount of goodwill for the year ended December 31, 2025 and December 31, 2024 was $10.5 million. The Company consists of one reporting unit. Management evaluates the reporting unit for impairment on an annual basis in the fourth quarter or more frequently if an event occurs or circumstances change that would more-likely-than-not reduce the fair value of the Company's reporting unit below its carrying value. There were no impairments in the carrying amount of goodwill for the year ended December 31, 2025 and December 31, 2024.

10. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities as of December 31, 2025 and 2024 consisted of the following (in thousands):

	December 31,	
	2025	2024
Research and development	$ 7,270	$ 1,625
Compensation and benefits	4,132	2,883
General and administrative	682	380
Commercial operations	—	534
Royalty payment	327	327
Lease liability, current	392	568
Total accrued expenses and other current liabilities	$ 12,803	$ 6,317

11. Capital Structure

Pursuant to the Company's amended and restated certificate of incorporation, the Company is authorized to issue two classes of stock; common stock and preferred stock. At December 31, 2025, the total number of shares of capital stock the Company was authorized to issue was 205,000,000 of which 200,000,000 was common stock and 5,000,000 was preferred stock. All shares of common and preferred stock have a par value of $0.001 per share.

AlmataBio Transaction

On March 27, 2024, the Company acquired AlmataBio in which the former AlmataBio stockholders received (i) 171,605 shares of the Company's common stock and (ii) 2,412 shares of the Company's Series C Preferred Stock. Upon Company stockholder approval, which was obtained on August 13, 2024 and subject to beneficial ownership limitations, 2,063 shares of the Series C Preferred Stock issued to the former AlmataBio stockholders automatically converted into 2,062,930 shares of common stock. Refer to Note 3 - Asset Acquisition for more information regarding the acquisition and refer to sub-header *"Series C Preferred Stock"* within the *"March 2024 Financing"* section below for more information regarding the Series C Preferred Stock.

March 2024 Financing

On March 28, 2024, the Company closed a private placement investment in which the investors received (i) 19,946 shares of non-voting convertible Series C Preferred Stock, and (ii) warrants to purchase up to an aggregate of 11,967,526 shares of Avalo's common stock (or a number of shares of Series C Preferred Stock convertible into the number of shares of common stock the warrant was then exercisable into), resulting in upfront gross proceeds of $115.6 million. Net proceeds were $108.1 million after deducting transaction costs of $7.5 million. The Company received an additional $69.4 million of gross proceeds upon the full exercise of the warrants in the fourth quarter of 2024. Net proceeds were $67.6 million after deducting $1.7 million of transaction costs. The private placement transaction costs and warrant exercise transaction costs were expensed within other (expense) income, net for the year ended December 31, 2024. Upon Company stockholder approval, which was obtained on August 13, 2024 and subject to beneficial ownership limitations, 6,585 shares of Series C Preferred Stock issued pursuant to the financing automatically converted into 6,585,314 shares of common stock. Additionally, the Company issued 781,259 shares of common stock and 11,186.267 shares of Series C Preferred Stock as a result of the warrant exercises in the fourth quarter of 2024.

Warrants on common stock or Series C Preferred Stock issued in March 2024 Financing

The warrants were exercisable via gross physical settlement for $5.796933 per underlying share of common stock (or a number of shares of Series C Preferred Stock convertible into the number of shares of common stock the warrant was then exercisable into). The warrants were fully exercised in the fourth quarter of 2024. The warrants included anti-dilution protection provisions.

The Company determined that the warrants did not satisfy the conditions to be accounted for as equity instruments. As the warrants did not meet the equity contract scope exception, the Company classified the warrants as a derivative liability upon issuance. The initial measurement of the warrants at fair value exceeded the proceeds received such that the difference between the initial fair value of the warrants and net upfront cash proceeds was recognized in the income statement as a loss. Subsequently, the warrants were carried at fair value with changes in fair value recognized in the Company's consolidated statements of operations and comprehensive loss until exercised. Upon exercise of the warrants in the fourth quarter of 2024, the warrant liability was valued at $73.3 million. The settlement of the $73.3 million warrant liability and related share issuance proceeds of $69.4 million resulted in a $142.7 million impact to additional-paid-in-capital in the fourth quarter of 2024. The classification of the Series C Preferred Stock in permanent equity is discussed below within the section "*Series C Preferred Stock issued in the AlmataBio Transaction, March 2024 Financing and upon Warrant Exercises*."

The valuation of the warrants was considered under Level 3 of the fair value hierarchy due to the need to use assumptions in the valuation that are both significant to the fair value measurement and unobservable. Refer to Note 6 - Fair Value Measurements for additional information regarding the settlement and valuation of the warrant liability.

Series C Preferred Stock issued in the AlmataBio Transaction, March 2024 Financing and upon Warrant Exercises

As of December 31, 2025, the Company had 5,000,000 shares of Preferred Stock authorized, of which 34,326 have been designated as Series C Preferred Stock. As of December 31, 2025, there were 18,792 shares of Series C Preferred Stock outstanding. The Series C Preferred Stock has a par value of $0.001 per share. The Series C Preferred Stock has no voting rights, no liquidation preference, and is not redeemable.

In the event of any liquidation, dissolution or winding up of the Company, holders of Series C Preferred Stock are entitled to be paid out of the assets with the Company legally available for distribution to its stockholders on an as-converted and pari-passu basis with common stock. The Series C Preferred Stock is subject to broad-based weighted average anti-dilution protection for certain issuances of common stock and securities convertible into common stock. The Series C Preferred Stock is entitled to receive dividends equal to and in the same form, and in the same manner, based on the then-current conversion ratio as dividends actually paid on shares of the common stock, when, as and if such dividends are paid on shares of the common stock.

As a result of a contract amendment in the fourth quarter of 2024, the Series C Preferred Stock met equity classification and was recognized as a component of permanent stockholders' equity within additional paid-in-capital. Prior to the contract amendment, the Series C Preferred Stock was contingently redeemable outside the control of the Company such that the Series C Preferred Stock was recognized outside of permanent equity. During the fourth quarter of 2024, the remaining 349 shares of Series C Preferred Stock held by the former AlmataBio stockholders, with a carrying value of $1.7 million, were reclassified to permanent equity. Additionally, the 11,186.267 shares of Series C Preferred Stock issued as a result of the warrant exercise in the fourth quarter of 2024, with a carrying value of $133.0 million, was recognized as a component of permanent stockholders' equity within additional-paid-in capital on the Company's unaudited condensed consolidated balance sheet.

No amounts were allocated to the Series C Preferred Stock issued pursuant to the March 2024 Financing because the initial fair value of the warrants exceeded gross proceeds received for the issuance of the private placement bundle that included both Series C Preferred Stock and warrants.

During the year ended December 31, 2025, an aggregate of approximately 6,104 shares of Series C Preferred Stock were converted to 6,103,560 shares of common stock. Subsequent to December 31, 2025, an aggregate of approximately 4,542 shares of Series C Preferred Stock were converted to 4,542,396 shares of common stock.

Series D and Series E Preferred Stock issued in the March 2024 Financing

As a condition to the March 2024 Financing, a single share of Series D Preferred Stock and a single Series E Preferred Stock were issued to two institutional investors that participated in the private placement. Both the Series D and the Series E Preferred Stock have a par value and liquidation preference of $0.001 per share. The Series D and Series E Preferred Stock do not have voting rights, are not entitled to dividends, and are not convertible into common stock. Each of the holders of the Series D and Series E Preferred Stock have the option to require the Company to redeem their shares at a price equal to the par value at any time. The Company retains the right to redeem the Series D and Series E Preferred Stock at a price equal to the par value if the holder owns less than a certain threshold of the Company's outstanding common stock. The Series D and Series E Preferred Stock do not provide the holders with substantive economics, and were issued solely to allow for the institutional investors to appoint a director to the Company's board of directors. Because the Series D and Series E Preferred Stock are redeemable at par value outside the control of the Company, they are recognized outside of permanent equity.

At-the-Market Offering Program

In June 2025, the Company entered into an "at-the-market" sales agreement with TD Securities (USA) LLC ("TD Cowen"), pursuant to which the Company may sell, from time to time, shares of its common stock having an aggregate offering price of up to $75.0 million through TD Cowen (the "ATM Program"). The Company sold 1.7 million shares of common stock for gross proceeds of $14.8 million and transaction costs of $0.4 million under the ATM Program during the year ended December 31, 2025.

Common Stock Warrants

At December 31, 2025, the following common stock warrants were outstanding:

Number of common shares underlying warrants	Exercise price per share	Expiration date
148	$ 7,488.00	June 2031

12. Stock-Based Compensation

Equity Incentive Plans, including 2016 Fourth Amended Plan and Inducement Plan

In April 2016, our board of directors adopted the 2016 Equity Incentive Plan, which was approved by our stockholders in May 2016 and which was subsequently amended and restated in May 2018 and August 2019 with the approval of our board of directors and our stockholders. Most recently, in June 2024, our board of directors approved a fourth amended and restated equity incentive plan, which was subsequently approved by the Company's stockholders in August 2024 (the "2016 Fourth Amended Plan"). During the term of the 2016 Fourth Amended Plan, the share reserve will automatically increase on the first trading day in January of each calendar year ending on (and including) January 1, 2034, by an amount equal to 5% of the total number of outstanding shares of common stock and Series C Preferred Stock (determined on an as-converted stock basis) plus all outstanding prefunded warrants to acquire shares of common stock (if any) as of December 31 of the preceding calendar year. As of December 31, 2025, there were 327,806 shares available for future issuance under the 2016 Fourth Amended Plan. On January 1, 2026, pursuant to the terms of the 2016 Fourth Amended Plan, an additional 1,865,256 shares were made available for issuance.

In September 2025, our board of directors adopted the 2025 Inducement Award Plan (the "Inducement Plan"). A total of 1,300,000 shares of our common stock were initially reserved for issuance under our Inducement Plan. Grants under the Inducement Plan can be granted to individuals who satisfy the standards for inducement grants under Nasdaq Listing Rule 5635(c)(4), including individuals who were not previously an employee or director of the Company or are following a bona fide period of non-employment, in each case as an inducement material to such individual's agreement to enter into employment with the Company. As of December 31, 2025, there were 811,000 shares available for future issuance under the Inducement Plan.

Option grants expire after ten years. Employee options typically vest over four years. Employees typically receive a new hire option grant, as well as an annual grant in the first or second quarter of each year. Options granted to non-employee directors typically vest immediately or over a period of one or three years. Non-employee directors may elect to receive stock options in lieu of board compensation, which vest immediately. For stock options granted to employees and non-employee directors, the estimated grant date fair market value of the Company's stock-based awards is amortized ratably over the individuals' service periods, which is the period in which the awards vest.

Stock-based Compensation Expense

Stock-based compensation expense includes expense related to stock options, restricted stock units, performance stock units and employee stock purchase plan shares. The amount of stock-based compensation expense recognized for the years ended December 31, 2025 and 2024 was as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Research and development	$ 5,992	$ 2,402
General and administrative	7,629	3,450
Total stock-based compensation	$ 13,621	$ 5,852

Stock options with service-based vesting conditions

The Company has granted stock options that contain service-based vesting conditions. The compensation cost for these options is recognized on a straight-line basis over the vesting periods. A summary of option activity for the year ended December 31, 2025 is as follows:

	Options Outstanding				
	Number of shares	Weighted average exercise price per share	Weighted average grant date fair value per share	Weighted average remaining contractual term (in years)	Aggregate Intrinsic Value[(1)] (in millions)
Balance at December 31, 2024	1,999,748	$ 19.91	$ 14.98	9.6	$ —
Granted	2,669,963	$ 8.72	$ 7.27		
Exercised	(78,362)	$ 9.88	$ 8.49		$ 0.6
Expired	(92)	$ 18,691.20	$ 7,524.87		
Balance at December 31, 2025	4,591,257	$ 13.20	$ 10.46	8.5	$ 39.9
Exercisable at December 31, 2025	953,658	$ 27.68	$ 20.11	6.5	$ 7.7

(1) The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock.

There were 1,026,613 options that vested during the year ended December 31, 2025, with a weighted average exercise price of $10.99 per share. The total grant date fair value of shares which vested during the years ended December 31, 2025 and 2024 was $9.6 million and $2.2 million, respectively.

The Company recognized stock-based compensation expense of $10.8 million and $4.5 million related to stock options with service-based vesting conditions for the years ended December 31, 2025 and 2024, respectively. At December 31, 2025, there was $25.1 million of total unrecognized compensation cost related to unvested service-based vesting conditions awards. This unrecognized compensation cost is expected to be recognized over a weighted-average period of 2.8 years.

On February 26, 2026, as part of its annual stock option award, the Company granted options with service-based vesting conditions to purchase 1.3 million shares of common stock to its employees that vest over four years.

The following table presents the assumptions used to compute stock-based compensation expense for stock options with service-based vesting conditions granted under the Black-Scholes valuation model for the years ended December 31, 2025 and 2024:

	Year Ended December 31,					
Service-based options	**2025**			**2024**		
Expected term of options (in years)	5.00	—	6.10	5.81	—	6.25
Expected stock price volatility	99.9%	—	113.1%	113.1%	—	116.9%
Risk-free interest rate	3.73%	—	4.45%	3.70%	—	4.26%
Expected annual dividend yield	0%			0%		

The valuation assumptions were determined as follows:

- **Expected term of options:** The expected term represents the period of time that options are expected to be outstanding. Due to lack of sufficient historical exercise data, the Company estimates the expected term of its stock options with service-based vesting granted to employees and members of the board of directors using the simplified method, which is an arithmetic average of the vesting term and the original contractual term of the option.

- **Expected stock price volatility:** The Company estimated the expected volatility based on a blend of Avalo's actual historical volatility of its stock price and the historical volatility of other similar publicly-traded biotechnology companies.

The Company calculated the historical volatility of the selected companies by using weekly closing prices over a period of the expected term of the associated award. The companies were selected based on their risk profiles, enterprise value, position within the industry, and historical stock price information sufficient to meet the expected term of the associated award. A decrease in the selected volatility would decrease the fair value of the underlying instrument.

- **Risk-free interest rate:** The Company bases the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected option term.

- **Expected annual dividend yield:** The Company estimated the expected dividend yield based on consideration of its historical dividend experience and future dividend expectations. The Company has never declared or paid dividends to stockholders. Moreover, it does not intend to pay dividends in the future, but instead expects to retain any earnings to invest in the continued growth of the business. Accordingly, the Company assumed an expected dividend yield of 0%.

Restricted Stock Units

The Company has granted RSUs that contain service-based vesting conditions. The Company measures the fair value of the RSUs using the stock price on the date of grant. The compensation cost for RSUs is recognized on a straight-line basis over the vesting period. A summary of RSU activity for the year ended December 31, 2025 is as follows:

	RSUs Outstanding	
	Number of shares	Weighted average grant date fair value
Balance at Unvested RSUs at December 31, 2024	632,100	$ 9.88
Vested	(217,036)	9.88
Forfeited	(28,000)	9.88
Unvested RSUs at December 31, 2025	387,064	$ 9.88

The RSUs, which were granted on August 13, 2024, vest annually over a three-year period beginning on March 28, 2025. Of the 217,036 RSUs vested during 2025, 55,017 were withheld on behalf of employees to satisfy RSU statutory tax withholding obligations. The Company recognized stock-based compensation expense of $2.3 million related to RSUs for the year ended December 31, 2025. At December 31, 2025, there was $2.4 million of total unrecognized compensation cost related to RSUs. The unrecognized compensation cost is expected to be recognized over a weighted-average period of 1.2 years.

Performance Stock Units

A PSU represents one equivalent share of our common stock to be issued after achievement of the performance goals specified in the grant. The Company estimates the fair value of our PSUs as of the grant date based upon the expected likelihood of achievement of the performance goals specified in the grant and the closing market price of our common stock on the date of grant. The Company recognizes stock-based compensation expense over the requisite service period, if it is probable that the performance goal will be achieved.

In August 2025, the Company granted PSUs to executives under the 2016 Fourth Amended Plan with a grant date fair value of $8.90 per unit (the "PSU Awards"). The PSU Awards include 492,500 shares that will be available to vest assuming 100% achievement of the performance metric, with a maximum of 738,750 shares available to vest assuming maximum achievement. The performance metric for the PSU Awards is based on the timing of data release and efficacy of the Company's Phase 2 LOTUS trial, and the achieved units may range from 0% to 150% of the target number depending on the level of achievement against the specified performance metric. Upon successful achievement of the performance metric, the PSU Awards will vest on the third anniversary of the grant date. As of December 31, 2025, the Company has not recognized any compensation expense related to the PSU Awards as the Company does not yet consider achievement of the performance metric to be probable.

Employee Stock Purchase Plan

On April 5, 2016, the Company's board of directors approved the 2016 Employee Stock Purchase Plan, which was approved by the Company's stockholders and became effective on May 18, 2016 (the "Initial ESPP").

In June 2024, our board of directors approved an amended and restated employee stock purchase plan, which was subsequently approved by the Company's stockholders in August 2024 (the "ESPP").

Under the ESPP, eligible employees can purchase common stock through accumulated payroll deductions at such times as are established by the administrator. The ESPP is administered by the compensation committee of the Company's board of directors. Under the ESPP, eligible employees may purchase stock at 85% of the lower of the fair market value of a share of the Company's common stock (i) on the first day of an offering period or (ii) on the purchase date. Eligible employees may contribute up to 15% of their earnings during the offering period.
The Company's board of directors may establish a maximum number of shares of the Company's common stock that may be purchased by any participant, or all participants in the aggregate, during each offering period. Under the ESPP, a participant may not accrue rights to purchase more than $25,000 of the fair market value of the Company's common stock for each calendar year in which such right is outstanding.

The Company initially reserved and authorized up to 174 shares of common stock for issuance under the Initial ESPP. Pursuant to the ESPP, on January 1 of each calendar year, the aggregate number of shares that may be issued under the ESPP automatically increases by a number equal to 1% of the Company's outstanding shares of common stock and Series C Preferred Stock (determined on an as-converted basis) plus all outstanding prefunded warrants to acquire shares of common stock (if any), as of December 31 of the preceding calendar year. As of December 31, 2025, 533,159 shares remained available for issuance. On January 1, 2026, the number of shares available for issuance under the ESPP increased by 373,051.

In accordance with the guidance in ASC 718-50, *Employee Share Purchase Plans*, the ability to purchase shares of the Company's common stock at the lower of the offering date price or the purchase date price represents an option and, therefore, the ESPP is a compensatory plan under this guidance. Accordingly, stock-based compensation expense is determined based on the option's grant-date fair value and is recognized over the requisite service period of the option. The Company used the Black-Scholes valuation model and recognized stock-based compensation expense of $0.5 million for the year ended December 31, 2025 and $0.1 million for the year ended December 31, 2024.

13. Income Taxes

The Company accounts for income taxes in accordance with ASC 740. ASC 740 is an asset and liability approach that requires the recognition of deferred tax assets and liabilities for the expected tax consequences or events that have been recognized in our financial statement or tax returns. ASC 740 also clarifies the accounting for uncertainty in income taxes recognized in the financial statements. The interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken, or expected to be taken, in a tax return. There were no significant matters determined to be unrecognized tax benefits taken or expected to be taken in a tax return that have been recorded in our financial statements for the year ended December 31, 2025. Tax years beginning in 2022 are generally subject to examination by taxing authorities, although net operating losses and tax credit carryforwards from all years are subject to examinations and adjustments for at least three years following the year in which the attributes are used.

ASC 740 provides guidance on the recognition of interest and penalties related to income taxes. There were no interest or penalties related to uncertain tax positions arising in the years ended December 31, 2025 and 2024. It is the Company's policy to treat interest and penalties, to the extent they arise, as a component of income taxes.

The income tax provision consisted of the following for the years ended December 31, 2025 and 2024 (in thousands):

	December 31,	
	2025	2024
Current:		
Federal	$ —	$ —
State	—	—
Total Current	—	—
Deferred:		
Federal	25	24
State	140	90
Total Deferred	165	114
Total Income Tax Expense	$ 165	$ 114

The net deferred tax assets (liabilities) consisted of the following for the years ended December 31, 2025 and 2024 (in thousands):

	December 31,	
	2025	2024
Deferred tax assets:		
Net operating losses	$ 61,737	$ 42,689
Tax credit carryforwards	7,675	6,263
Capitalized research and development	8,161	10,803
Stock-based compensation	3,260	1,651
Basis difference in tangible and intangible assets, net	1,586	1,811
Accrued compensation	1,041	691
Installment sale	496	462
Derivative liability	4,723	2,073
Other	13	148
Lease liability	112	225
Valuation allowance	(87,559)	(65,656)
Total net deferred tax assets	1,245	1,160
Deferred tax liabilities:		
Goodwill	(1,249)	(1,022)
Prepaid expenses	(342)	(227)
Right-of-use asset	(88)	(181)
Total net deferred tax liabilities	(1,679)	(1,430)
Deferred tax liability, net	$ (434)	$ (270)

As of December 31, 2025, the Company had approximately $255.0 million of gross net operating losses for federal and state tax purposes that do not expire and $3.4 million that will begin to expire in 2031. As of December 31, 2025, the Company has various research tax credits of $7.7 million that will begin to expire in 2038.

The income tax expense for the years ended December 31, 2025 and 2024 differed from the amounts computed by applying the U.S. federal income tax rate of 21% as follows:

	December 31,			
	2025		2024	
	Amount	Percent	Amount	Percent
U.S. Federal statutory rate	$ (16,400)	21.0 %	$ (7,353)	21.0 %
State and Local Income Tax, Net of Federal Income Tax Effect	140	(0.2)%	90	(0.3)%
Tax Credits (Research & Development)	(1,412)	1.7 %	(409)	1.2 %
Changes in Valuation Allowances	16,656	(21.3)%	5,816	(16.6)%
Nontaxable or Nondeductible Items				
Warrants and related transaction costs	—	— %	(6,954)	19.9 %
Acquired in-process research and development	—	— %	5,805	(16.6)%
Stock compensation	353	(0.4)%	3,846	(11.0)%
Executive Compensation	821	(1.0)%	(564)	1.6 %
Other	6	— %	2	— %
Other Adjustments	1	— %	(165)	0.5 %
Effective Tax Rate	$ 165	(0.2)%	$ 114	(0.3)%

State taxes included in the rate reconciliation above are primarily related to deferred tax expense recognized related to Pennsylvania in 2025, and Pennsylvania and Maryland in 2024.

The valuation allowance recorded by the Company as of December 31, 2025 and 2024, resulted from the uncertainties of the future utilization of deferred tax assets mainly resulting from net operating loss carry forwards for federal and state income tax purposes as well as the federal research and experimental and orphan drug tax credits. The ultimate realization of the deferred tax assets is dependent upon generation of future taxable income during the periods in which temporary differences are expected to reverse. The Company concluded it is more likely than not that a significant portion of its remaining gross deferred tax assets less the reversal of deferred tax liabilities will not be realized in the future, accordingly, a valuation allowance continues to be recorded against the Company's remaining deferred tax asset as of December 31, 2025 and December 31, 2024.

The Company will continue to assess and evaluate strategies that will enable the deferred tax asset, or portion thereof, to be utilized, and will reduce the valuation allowance appropriately at such time when it is determined that the "more likely than not" criteria is satisfied.

Sections 382 and 383 of the IRC subject the future utilization of net operating losses and certain other tax attributes, such as research and experimental tax credits, to an annual limitation in the event of certain ownership changes, as defined. The Company has undergone an ownership change study through June 2020 and has determined that a "change in ownership" as defined by IRC Section 382 of the Internal Revenue Code of 1986, as amended, and the rules and regulations promulgated thereunder, did occur in February 2012, July 2014, and April 2017. Based on the Company having undergone multiple ownership changes throughout their history, these NOLs will free up at varying rates each year. Subsequent to the changes in ownership previously listed, the NOL and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period. This could limit the amount of NOLs and research and development credits that the Company can utilize annually to offset future taxable income or tax liabilities. Subsequent ownership changes may further affect the limitation in future years. The Company is analyzing the potential impact of its equity financings on beneficial ownership from June 30, 2020 to December 31, 2025, which could result in the entire NOL carryforward balance being subject to any additional IRC Section 382 and 383 limitations. To the extent there is a limitation, there could be a reduction in the $8.4 million deferred tax asset related to federal loss carryforwards and tax credits that may have expired unutilized with an offsetting reduction in the valuation allowance.

All of the Company's tax years are currently open to examination by each tax jurisdiction in which the Company is subject to taxation.

14. Commitments and Contingencies

Litigation

Litigation – General

The Company may become party to various contractual disputes, litigation, and potential claims arising in the ordinary course of business. Reserves are established in connection with such matters when a loss is probable and the amount of such loss can be reasonably estimated. The Company currently does not believe that the resolution of such matters will have a material adverse effect on its financial position or results of operations except as otherwise disclosed in this report.

Possible Future Milestone Payments for In-Licensed Compounds

General

Avalo is a party to license and development agreements with various third parties, which contain future payment obligations such as royalties and milestone payments. The Company recognizes a liability (and related expense) for each milestone if and when such milestone is probable and can be reasonably estimated. As typical in the biotechnology industry, each milestone has unique risks that the Company evaluates when determining the probability of achieving each milestone and the probability of success evolves over time as the programs progress and additional information is obtained. The Company considers numerous factors when evaluating whether a given milestone is probable including (but not limited to) the regulatory pathway, development plan, ability to dedicate sufficient funding to reach a given milestone and the probability of success.

Abdakibart (AVTX-009)

On March 27, 2024, Avalo obtained the rights to an anti-IL-1β mAb (abdakibart (AVTX-009)), including the world-wide exclusive license from Eli Lilly and Company ("Lilly") (the "Lilly License Agreement"), pursuant to its acquisition of AlmataBio. AlmataBio had previously purchased the rights, title and interest in the asset from Leap Therapeutics, Inc. ("Leap") in 2023, which have since been assumed by Avalo pursuant to its acquisition of AlmataBio (the "Leap Agreement"). Avalo is responsible for the development and commercialization of the program.

Avalo is required to pay up to $70.0 million based on the achievement of specified development and regulatory milestones to Lilly. Upon commercialization, the Company is required to pay sales-based milestones aggregating up to $650.0 million payable to Lilly and $70.0 million payable to Leap. There are no annual or maintenance fees payable under the Lilly License Agreement and Leap Agreement. Additionally, Avalo is required to pay royalties to Lilly during a country-by-country royalty term in which the low end and the high end of the range fall between 5% and 15% of Avalo or its sublicensees' annual net sales. The royalty term due to Lilly commences on the date of first commercial sale of the licensed product in a given territory and expires on a county-by-country basis; on the latest of (a) the tenth (10th) anniversary of the date of the first commercial sale, (b) the expiration of the last-to-expire licensed patent in the given territory, or (c) the expiration of any data exclusivity period for the licensed product in the given territory.

The Lilly License Agreement remains in effect until the expiration of the last-to-expire royalty term of any licensed products. Each party may terminate for cause or by mutual agreement though the Company may terminate at its sole discretion by giving one-hundred twenty (120) days' prior written notice to Lilly, in which case all licenses and rights granted pursuant to the agreement shall automatically terminate and revert to Lilly. There are no termination or expiration provisions under the Leap Agreement.

Avalo has not paid any milestones, royalties or any other amounts under the Lilly License Agreement or Leap Agreement.

No expense related to the agreements was recognized in the year ended December 31, 2025. There has been no cumulative expense recognized as of December 31, 2025 under the agreements. The Company will continue to monitor the milestones and royalties at each reporting period.

Refer to the sub-header below entitled "Acquisition Related and Other Contingent Liabilities" for information regarding future development milestones that are payable to the former AlmataBio stockholders.

Quisovalimab (AVTX-002) Agreements

KKC License Agreement

On March 25, 2021, the Company entered into a license agreement with Kyowa Kirin Co., Ltd. ("KKC") for exclusive worldwide rights to develop, manufacture and commercialize quisovalimab, KKC's first-in-class fully human anti-LIGHT (TNFSF14) monoclonal antibody for all indications (the "KKC License Agreement"). The KKC License Agreement replaced the Amended and Restated Clinical Development and Option Agreement between the Company and KKC dated May 28, 2020. Avalo is responsible for the development and commercialization of quisovalimab in all indications worldwide (other than the option in the KKC License Agreement that, upon exercise by KKC, allows KKC to develop, manufacture and commercialize quisovalimab in Japan). Avalo is not currently pursuing the clinical development of quisovalimab and is exploring strategic alternatives.

Under the KKC License Agreement, the Company paid KKC an upfront license fee of $10.0 million, which we recognized within research and development expenses in 2021. Avalo is also required to pay KKC up to an aggregate of $112.5 million based on the achievement of specified development and regulatory milestones. Upon commercialization, the Company is required to make milestone payments to KKC aggregating up to $75.0 million tied to the achievement of annual net sales targets. There are no annual or maintenance fees payable under the KKC License Agreement.

Additionally, the Company is required to pay KKC royalties during a country-by-country royalty term equal to a mid-teen percentage of annual net sales. The Company is required to pay KKC a mid-twenties percentage of the payments that the Company receives from sublicensing of its rights under the KKC License Agreement, subject to certain exclusions. The royalty term due to KKC commences on the date of first commercial sale of the licensed product in a given territory and expires on a county-by-country basis, on the latest of (a) the twelfth (12th) anniversary of the date of the first commercial sale, (b) the expiration of the last-to-expire licensed patent in the given territory, or (c) the expiration of any data exclusivity period for the licensed product in the given territory.

The KKC License Agreement remains in effect while the Company and its affiliates and sublicensees develop and commercialize quisovalimab subject to customary termination rights. Each party may terminate for cause, though Avalo may terminate for convenience upon six (6) months' prior written notice in the case where regulatory approval has not been obtained for the licensed product or upon twelve (12) months' prior written notice where regulatory approval has been obtained for the licensed product.

As disclosed above, Avalo paid the $10.0 million upfront license fee in 2021. No further amounts have been paid related to the milestones, royalties or any other amounts under the agreement.

No expense related to the KKC License Agreement was recognized in the year ended December 31, 2025. There has been no cumulative expense recognized as of December 31, 2025 related to the milestones, royalties or any other amounts other than the $10.0 million upfront license fee incurred in 2021 as disclosed above. The Company will continue to monitor the milestones and royalties at each reporting period.

CHOP License Agreement

Following its February 3, 2020 merger with Aevi Genomic Medicine, Inc. ("Aevi"), the Company became party to a license agreement with The Children's Hospital of Philadelphia ("CHOP") (as amended, the "CHOP License Agreement"). Quisovalimab became a covered product under this license agreement in 2021 and at that time became subject to the terms therein. Avalo is not currently pursuing the clinical development of quisovalimab and is exploring strategic alternatives.

An initial upfront fee of $0.5 million was paid to CHOP by Aevi, which Avalo acquired in 2020. Avalo is required to pay an additional $1.0 million to CHOP based on the achievement of specified regulatory and commercial milestones Avalo is obligated to pay an annual license maintenance fee of $0.2 million to CHOP, of which Avalo has paid an aggregate of $1.3 million as of the filing date of this Annual Report on Form 10-K.

The Company is also obligated to pay tiered royalties to CHOP on a country-to-country basis in which the low end and high end of the range are single-digit royalties based on the Company's net sales of quisovalimab. The royalty term extends to the later of (a) fifteen years following the original date of the CHOP License Agreement, (b) the last-to-expire of the valid claims in the licensed patent rights covering the manufacture, sale, or use of quisovalimab and (c) the expiration of the regulatory exclusivity period for quisovalimab.

CHOP may terminate the CHOP License Agreement for the material default or insolvency of the Company, and the Company may terminate the CHOP License Agreement at will with six (6) months' written notice.

As disclosed above, Aevi paid the $0.5 million upfront license fee and Avalo has paid $1.3 million of annual license fees. No further amounts have been paid related to the milestones, royalties or any other amounts under the agreement.

No expense related to the milestones and royalties due under the CHOP Agreement was recognized for the year ended December 31, 2025. Avalo has not recognized any cumulative expense under the agreement related to the milestone or royalties as of December 31, 2025. The Company will continue to monitor the milestones and royalties at each reporting period.

AVTX-006 Astellas License Agreement

On July 15, 2019, the Company entered into an exclusive license agreement with OSI Pharmaceuticals, LLC, an indirect wholly owned subsidiary of Astellas Pharma, Inc. ("Astellas"), for the worldwide development and commercialization of the novel, second generation mTORC1/2 inhibitor (AVTX-006). Avalo is fully responsible for the development and commercialization of the program. Avalo is not currently pursuing the clinical development of AVTX-006 and is exploring strategic alternatives.

Under the terms of the license agreement, there was an upfront license fee of $0.5 million. The Company is required to pay Astellas up to an aggregate of $5.5 million based on the achievement of specified development and regulatory milestones. There are no annual maintenance fees payable under the Astellas license agreement. Additionally, the Company is required to pay Astellas a tiered mid-to-high single digit percentage of the payments that Avalo receives from any sublicensing of its rights under the Astellas license agreement, subject to certain exclusions. Upon commercialization, the Company is required to pay Astellas royalties during a country-by-country royalty term equal to a tiered mid-to-high single digit percentage of annual net sales during the period beginning upon the date of the first commercial sale of such licensed product in such country and ending on the later to occur of (a) the expiry of the last valid claim of an OSI product patent covering such licensed product in such country, (b) expiration of regulatory exclusivity in such country, and (c) ten (10) years from the first commercial sale of such licensed product in such country.

The Astellas License Agreement remains in effect on a country-by-country and licensed product-by-licensed product basis (in the territory), unless the license agreement is terminated earlier in accordance with the license agreement. Avalo may terminate the agreement at any time upon providing sixty (60) days' written notice to Astellas and may terminate the agreement in its entirety without cause.

As disclosed above, Avalo paid the $0.5 million upfront license fee. No further amounts have been paid related to the milestones, royalties or any other amounts under the agreement.

No expense related to this license agreement was recognized in the year ended December 31, 2025. There has been $0.5 million of cumulative expense recognized as of December 31, 2025 related to the milestones under this license agreement. The Company will continue to monitor the remaining milestones and royalties at each reporting period.

Possible Future Milestone Proceeds for Out-Licensed Compounds

AVTX-301 Out-License

On May 28, 2021, the Company out-licensed its rights in respect of its non-core asset, AVTX-301, to Alto Neuroscience, Inc. ("Alto"). The Company initially in-licensed the compound from an affiliate of Merck & Co., Inc. in 2013. Alto is fully responsible for the development and commercialization of the program.

Under the out-license agreement, the Company received a mid-six digit upfront payment from Alto, which we recognized as license revenue in 2021. The Company is also eligible to receive up to an aggregate of $18.6 million based on the achievement of specified development, regulatory and commercial sales milestones. Additionally, the Company is entitled to a less than single digit percentage royalty based on annual net sales.

The out-license agreement remains in effect on a licensed product-by-licensed product and country-by-country basis until the later of (i) the expiration of the last to expire valid patent claim covering such licensed product in such country, or (ii) 10 (ten) years after the first commercial sale of such licensed product in such country. Upon expiration of the agreement, the licenses shall become a fully paid-up, royalty-free, irrevocable, perpetual non-exclusive license and sublicense.

The Company had not recognized any milestones as of December 31, 2025 or received any payments other than the upfront payment as disclosed above.

AVTX-406 License Assignment

On June 9, 2021, the Company assigned its rights, title, interest, and obligations under an in-license covering its non-core asset, AVTX-406, to ES, a wholly owned subsidiary of Armistice, who was a significant stockholder of the Company at the time of the transaction and whose chief investment officer, Steven Boyd, and managing director, Keith Maher, served on Avalo's Board until August 8, 2022. The transaction with ES was approved in accordance with Avalo's related party transaction policy. ES is fully responsible for the development and commercialization of the program.

Under the assignment agreement, the Company received a low-six digit upfront payment from ES, which we recognized as license revenue in 2021. The Company is also eligible to receive up to an aggregate of $6.0 million based on the achievement of specified development and regulatory milestones. Upon commercialization, the Company is eligible to receive sales-based milestone payments aggregating up to $20.0 million tied to annual net sales targets.

The Company had not recognized any milestones as of December 31, 2025 or received any payments other than the upfront payment as disclosed above.

AVTX-800 Series Asset Sale

On October 27, 2023, the Company sold its rights, title and interests in AVTX-801, AVTX-802 and AVTX-803 to AUG. AUG is fully responsible for the development and commercialization of the program.

Pursuant to the Purchase Agreement with AUG, the Company received an upfront payment of $0.2 million. Additionally, AUG assumed aggregate liabilities of $0.4 million, which included certain liabilities incurred prior to the date of the Purchase Agreement, costs due and payable between the date of the Purchase Agreement and the closing date, and obligations under 800 Series contracts assumed by AUG. Avalo is also entitled to a contingent milestone payment of 20% of certain amounts, if any, granted to AUG upon sale of any priority review voucher related to the 800 Series compounds granted to AUG by the FDA, net of any selling costs, or $15.0 million for each compound (for a potential aggregate of $45.0 million) if the first FDA approval is for any indication other than a Rare Pediatric Disease (as defined in the Purchase Agreement).

The Company had not recognized any revenue related to the milestones as of December 31, 2025 or received any payments other than the upfront payment and reimbursement for certain liabilities as disclosed above.

Acquisition Related and Other Contingent Liabilities

AlmataBio Transaction Possible Future Milestone Payments

On March 27, 2024, the Company acquired abdakibart (AVTX-009) through its acquisition of AlmataBio. Pursuant to the AlmataBio Transaction, the Company made a cash payment of $7.5 million in April 2024 to the former AlmataBio stockholders, which was due upon the initial closing of the private placement on March 28, 2024 (the "Initial Milestone"). Further, a portion of the consideration for the AlmataBio transaction includes development milestones to the former AlmataBio stockholders including $5.0 million due upon the first patient dosed in a Phase 2 trial in patients with hidradenitis suppurativa for abdakibart (AVTX-009) (the "Second Milestone"), which was met and paid in October 2024 as discussed below, and $15.0 million due upon the first patient dosed in a Phase 3 trial for abdakibart (AVTX-009) (the "Third Milestone"), both of which are payable in cash or stock of Avalo at the election of the former AlmataBio stockholders. In the absence of timely notice of such election, Avalo may elect to pay the milestones in cash or common stock of Avalo.

The Company paid the Initial Milestone payment in April 2024 and recognized the payment within acquired in-process research and development expense in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2024. In addition, the Company concluded the Second Milestone was probable as of the acquisition date and therefore recognized the $5.0 million milestone at that time within acquired in-process research and development expense. The Company made a cash payment of $5.0 million in October 2024 upon meeting the Second Milestone. The Company will continue to monitor the Third Milestone each reporting period.

AVTX-006 Royalty Agreement with Certain Related Parties

In July 2019, Aevi entered into a royalty agreement, and liabilities thereunder were assumed by Avalo upon close of the Aevi Merger in February 2020. The royalty agreement provided certain investors, including LeoGroup Private Investment Access, LLC on behalf of Garry Neil, the Company's Chief Executive Officer and Chairman of the Board, and Mike Cola, the Company's former Chief Executive Officer (collectively, the "Investors"), a royalty stream, in exchange for a one-time aggregate payment of $2.0 million (the "Royalty Agreement"). Pursuant to the Royalty Agreement, the Investors will be entitled collectively to an aggregate amount equal to a low-single digit percentage of the aggregate net sales of the Company's second generation mTORC1/2 inhibitor, AVTX-006, for a royalty term consistent with the royalty term disclosed in the AVTX-006 Astellas License Agreement section above. Avalo considers AVTX-006 a non-core asset and is exploring strategic alternatives. At any time beginning three years after the date of the first public launch of AVTX-006, Avalo may exercise, at its sole discretion, a buyout option that terminates any further obligations under the Royalty Agreement in exchange for a payment to the Investors of an aggregate of 75% of the net present value of the royalty payments. A majority of the independent members of the board of directors and the audit committee of Aevi approved the Royalty Agreement.

Avalo assumed this Royalty Agreement upon closing of the Aevi Merger and it is recorded as a royalty obligation within the Company's accompanying consolidated balance sheet as of December 31, 2025 and December 31, 2024. Because there is a significant related party relationship between the Company and the Investors, the Company has treated its obligation to make royalty payments under the Royalty Agreement as an implicit obligation to repay the funds advanced by the Investors. As the Company makes royalty payments in accordance with the Royalty Agreement, it will reduce the liability balance. At the time that such royalty payments become probable and estimable, and if such amounts exceed the liability balance, the Company will impute interest accordingly on a prospective basis based on such estimates, which will result in a corresponding increase in the liability balance.

15. Segments

Our CODM, our Chief Executive Officer, views the Company's operations and manages the business as one operating segment. The presentation of financial results as one reportable segment is consistent with the way we operate our business and is consistent with the manner in which our CODM evaluates performance and makes resource and operating decisions for the business. The accounting policies of the business segment are the same as those described in the summary of significant accounting policies.

The CODM evaluates performance and makes resource and operating decisions for the business based on net loss that is reported on the consolidated statement of operations and total assets as reported on the consolidated balance sheet. The CODM's primary evaluation of the Company's success is the ability to progress its research and development pipeline programs toward commercialization or opportunistically out-license rights to indications or geographies. The CODM uses net loss compared to budget and/or forecast amounts to evaluate this progress to make resource and operating decisions such as whether to issue equity and/or make new investments in additional indications or pipeline assets. Additionally, the Company's CODM periodically reviews research and development expense, as stated on the consolidated statement of operations, and treats it as a significant segment expense. The CODM considers research and development expense in the context of achieving the next expected milestone in the pipeline, and will make resource and operating decisions accordingly, such as decisions on raising additional capital and/or pursuing additional indications or programs. The following table summarizes our research and development expenses for the years ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Nonclinical expenses	$ 824	$ 570
Clinical expenses	24,865	9,966
CMC expenses	9,657	5,106
Internal expenses:		
Salaries, benefits and related costs	8,502	6,164
Stock-based compensation expense	5,992	2,402
Other	244	229
Research and development	$ 50,084	$ 24,437

CORPORATE INFORMATION

Directors

Michael Heffernan, *Chairman of the Board*

Garry Neil, M.D., *Chief Executive Officer*

Mitchell Chan

Jonathan Goldman, M.D.

Rita Jain, M.D.

Aaron Kantoff

Gilla Kaplan, Ph.D.

Kevin Lind

Samantha Truex

Officers

Garry Neil, M.D., *Chief Executive Officer*

Taylor Boyd, *Chief Business Officer*

Mittie Doyle, M.D., FACR, *Chief Medical Officer*

Jennifer Riley, *Chief Strategy Officer*

Christopher Sullivan, *Chief Financial Officer*

Paul Varki*, Chief Legal Officer*

Headquarters

1500 Liberty Ridge Drive, Suite 321
Wayne, Pennsylvania 19087
(410) 522-8707

Transfer Agent

Equiniti Trust Company, LLC
28 Liberty Street, 53rd Floor
New York, New York 10005
(718) 921-8200

Website

www.avalotx.com

Stock Listing

Avalo Therapeutics, Inc.'s common stock is listed on the Nasdaq Capital Market and quoted under the symbol "AVTX."

1500 Liberty Ridge Drive, Suite 321
Wayne, Pennsylvania 19087
Phone: (410) 522-8707
www.avalotx.com