2024 ANNUAL REPORT

Included in the 2024 Annual Report:
Form 10-K (without exhibits) filed with the U.S. Securities and Exchange Commission on March 20, 2025

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, 2024

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.)

540 Gaither Road, Suite 400
Rockville, Maryland 20850
(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 28, 2024 (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 $12.9 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 17, 2025, there were 10,671,934 outstanding shares of the registrant’s common stock, par value $0.001 per share.

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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. 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 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.

- 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 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 AVTX-009 increases the risk of such exposure.

- The marketing approval processes of the United States Food and Drug Administration (the "FDA") and comparable foreign 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.

- We use third parties to manufacture all of our product candidates. This may increase the risk that we will not have sufficient quantities of our product candidates to conduct our clinical trials or for commercial production or whether we can acquire such quantities at an acceptable cost, which could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates.

- 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 cease our operations.

- 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 patent for AVTX-009 is set to expire in 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 market price of our stock is volatile, and you could lose all or part of your investment.

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

PART I

Item 1. Business.

Overview

Avalo Therapeutics, Inc. (the "Company", "Avalo" or "we") is a clinical stage biotechnology company focused on the treatment of immune dysregulation. Avalo's lead asset is AVTX-009, an anti-IL-1β monoclonal antibody ("mAb"), targeting inflammatory diseases.

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

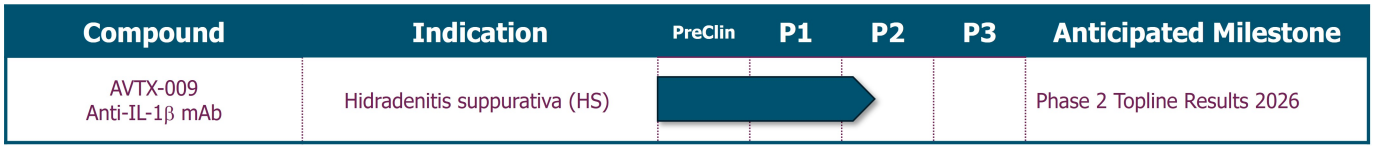
Our Strategy

Our strategy for increasing stockholder value includes:

- Advancing our pipeline through development to regulatory approval. Most notably and in the near term, completing our Phase 2 LOTUS trial in hidradenitis suppurativa, preparing for the next stage of development for that indication and considering further indication expansion for AVTX-009;
- Acquiring or in-licensing rights to and/or developing targeted, complementary differentiated preclinical and clinical stage compounds that treat immune mediated disease; and
- Opportunistically out-license rights to compounds, indications or geographies.

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; 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. 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. Even if the FDA approves a product, it may impose post-approval requirements or withdraw approval if safety or efficacy issues arise. 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.

Pipeline — Overview, Competition, and Intellectual Property



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

Overview: 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 central driver in the inflammatory process. Overproduction or dysregulation of IL-1β is implicated in many autoimmune and inflammatory diseases. IL-1β is a major, validated target for therapeutic intervention. There is evidence that inhibition of IL-1β could be effective in hidradenitis suppurativa, a chronic, often debilitating inflammatory skin disease that causes painful lumps, abscesses and tunnels to form under the skin ("HS"), and a variety of other inflammatory diseases in dermatology, gastroenterology, and rheumatology. Note that 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.

In October 2024, Avalo dosed its first patient in its Phase 2 ("LOTUS") trial of AVTX-009 in HS. The LOTUS Trial is a randomized, double-blind, placebo-controlled, parallel-group Phase 2 trial with two AVTX-009 dose regimens to evaluate the efficacy and safety of AVTX-009 in approximately 180 adults with moderate to severe HS. Subjects are randomized (1:1:1) to receive either one of two doses of AVTX-009 or placebo during a 16-week treatment phase. The primary efficacy endpoint is the proportion of subjects achieving Hidradenitis Suppurativa Clinical Response (HiSCR75) at Week 16. We are the study sponsor and the current trial locations include the United States, Canada, France, Germany, Italy, Spain, Bulgaria, Czech Republic, Greece, Poland, Australia, Turkey, and Slovakia.

Secondary endpoints include the following:

- Incidence of adverse events ("AEs"), and changes from Baseline in vital signs, physical examinations, and clinical laboratory tests
- The proportion of subjects achieving HiSCR50 by visit
- The proportion of subjects achieving HiSCR90 by visit
- Change from Baseline in International HS Severity Score System ("IHS4")
- Change from Baseline in Abscess and Inflammatory Nodule ("AN") count
- Change from Baseline in draining fistula count
- Percentage of subjects achieving at least a 30% reduction and at least a 1 unit reduction from Baseline on a Numerical Rating Scale ("NRS") in Patient's Global Assessment of Skin Pain ("PGA Skin Pain") among subjects with Baseline NRS ≥3 ("NRS30")
- Percentage of subjects with flares defined as ≥25% increase in AN count plus an increase of ≥2 in AN count compared to Baseline
- Incidence of AVTX-009 anti-drug antibodies ("ADA") at specified timepoints

In addition to HS, Avalo intends to develop AVTX-009 in at least one other chronic inflammatory indication.

Competition: We face substantial competition from major pharmaceutical companies and biotechnology companies worldwide. 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 is one company with an approved anti-IL-1β antibody (Novartis AG or "Novartis") and Avalo is one of four additional companies with novel, non-biosimilar antibodies specifically targeting IL-1β in clinical development worldwide (such as Novartis and Sunshine Guojian Pharmaceutical Co Ltd, or "Sunshine Guojian"), 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-1α as well as IL-1β 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, five additional companies have 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.

License: 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"). Avalo obtained the rights to AVTX-009, including the Lilly License Agreement and Leap Agreement, pursuant to its acquisition of AlmataBio in the first quarter of 2024 (the "AlmataBio Transaction"). Avalo is responsible for the development and commercialization of the program.

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

Additionally, Avalo is required to pay royalties to Lilly of between 5% and 15% of Avalo or its sublicenees' annual net sales, beginning on first commercial sale of a licensed product in a given territory and expiring on a county-by-country basis, on the latest of (a) the tenth (10^{th}) 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.

Avalo has 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 the Company may terminate at its 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.

Pursuant to the AlmataBio Transaction, the Company made a cash payment of $7.5 million due 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 AVTX-009 and $15.0 million due upon the first patient dosed in a Phase 3 trial for 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 made the $5.0 million payment in cash.

Market, Data, and Patent Exclusivity: If we receive marketing approval, we expect to receive biologics reference product exclusivity in the United States, which may provide twelve years of data exclusivity in the United States from the date of FDA approval and ten years of combined data and market exclusivity in Europe (the EU and UK) from the date of approval. We plan to primarily rely on biologics data or market exclusivity; however, the table below sets forth details of a patent related to AVTX-009 that might provide additional protection that the Company considers material:

Product	Jurisdiction	Owned/Licensed	Status	Expiration Date	Protection Type
AVTX-009	United States	Licensed	Issued	2026	Composition of Matter

Legacy Programs

We are not currently pursuing the clinical development of the following Company 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.

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 others and to prevent others from infringing our proprietary rights.

We hold ownership, trademark rights and/or exclusivity to develop and commercialize our product candidates covered by patents and patent applications. Our portfolio of patents includes patents or patent applications with claims directed to compositions of matter, including compounds, pharmaceutical formulations, methods of use, methods of manufacturing the compounds, or a combination of these claims. 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 under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. Similar extensions to patent term may be available in other countries for particular patents in our portfolio.

We plan to augment our portfolio of compounds by focusing on the development (when possible) of new chemical entities ("NCEs") or biologics, which have not previously received FDA approval. Upon approval by the FDA, NCEs are entitled to market and data exclusivity in the United States with respect to generic drug competition for a 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 for a period of twelve years from the date of FDA approval, even if the related patents have expired.

Intellectual property for AVTX-009 is discussed above.

Competition Overview

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.

Competition for AVTX-009 is discussed above.

Manufacturing

We do not have any manufacturing facilities. We rely on contract manufacturing organizations to produce our drug candidates in accordance with applicable provisions of the FDA's and EMA's current good manufacturing practices ("cGMP") regulations for use in our clinical studies. The manufacture of pharmaceuticals is subject to extensive cGMP regulations, which impose various procedural and documentation requirements and govern all areas of record keeping, production processes and controls, personnel and quality control.

Sales and Marketing

We may retain or partner with third parties on the commercialization rights and develop sales and marketing capabilities, when needed. 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 Risks

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. 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.

Many of our competitors have products that have been approved or are in advanced development. We face competition from other companies, academic institutions, governmental agencies and other public and private research organizations for collaborative arrangements with pharmaceutical and biotechnology companies, in recruiting and retaining highly qualified scientific and management personnel and for licenses to additional technologies.

Our competitors, either alone or with their collaborators, may succeed in developing technologies or drugs that are more effective, safer, and more affordable or more easily administered than our product candidates and may achieve patent protection or commercialize drugs sooner than us. Developments by others may render our product candidates or our technologies obsolete. Our failure to compete effectively could have a material adverse effect on our business.

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, promoting, distributing, marketing, importing and exporting, pricing, and government contracting related to pharmaceutical products such as those we are developing.

United States Government Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations. The process of obtaining marketing approvals and the 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, or other actions, such as the FDA's delay in review of or refusal to approve a pending new 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, requests for 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.

FDA Marketing Approval

Obtaining FDA marketing approval for new products 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 IND under which human studies are conducted. Human testing is generally conducted under an IND in three phases following Good Clinical Practices ("GCP") regulations:

- Phase 1: Studies evaluate the safety and tolerability of the drug, generally in normal, healthy volunteers;
- Phase 2: Studies 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 evaluate safety and efficacy of the product at specific doses in one or more larger pivotal trials.

In addition to human testing, the manufacturing process of the potential product must be developed in accordance with cGMP regulations. Prior to the approval of a new product, the FDA may inspect the facilities at which the proposed drug product is to be manufactured to ensure cGMP compliance. FDA may also inspect clinical trial sites and applicable laboratories.

In addition to the cumulative safety and efficacy data generated from the clinical trials described above, chemistry, manufacturing and control ("CMC") information, nonclinical study data and proposed labeling form the basis to support approval of an NDA or BLA to the FDA. 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"). 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, the Sponsor of the application must resolve the deficiencies and re-submit the application, re-starting 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, in order for FDA approval.

Even with submission of this additional information, the FDA may decide that the NDA or BLA does not satisfy the regulatory criteria for approval. 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.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1: The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- Phase 2: The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3: The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

The development and approval of new drugs requires substantial time, effort and financial resources. Data obtained from a development program is not always conclusive and may be susceptible to varying interpretations. These instances 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 application 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, but they are not required by statute or regulation. The FDA may also impose post-marketing requirements as a condition of approval of an NDA or BLA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials and surveillance, to further assess and monitor the product's safety and effectiveness after commercialization. Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product becomes available in the market. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market 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, most 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 any marketed product and new application fees for supplemental applications with clinical data. Additionally, the FDA strictly regulates the labeling, advertising and promotion of products under an approved NDA or BLA. The FDA and other agencies actively 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.

Other Regulations of the Healthcare Industry

In addition to FDA regulations governing the marketing of pharmaceutical products, there are various state and federal laws that may restrict business practices in the biopharmaceutical industry. These include the following:

- The federal Anti-Kickback laws and implementing regulations, which prohibit persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- Other Medicare laws, regulations, rules, manual provisions and policies that prescribe the requirements for coverage and payment for pharmaceutical products and services, including the amount of such payment;
- The federal False Claims Act, which imposes civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government;
- The Foreign Corrupt Practices Act ("FCPA"), which prohibits certain payments made to foreign government officials; and
- State and foreign law equivalents of the foregoing and state laws regarding pharmaceutical company marketing compliance, reporting and disclosure obligations.

If our agents or operations are found to be in violation of any of these laws, regulations, rules or policies or any other law or governmental regulation, or if interpretations of the foregoing change, we may be subject to civil and criminal penalties, damages, fines, exclusion from participating in the Medicare and Medicaid programs and the curtailment or restructuring of our operations.

To the extent that any of our product candidates are approved for sale in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Coverage and Reimbursement

Our ability to commercialize and, the commercial success of, any approved product candidates will depend in part on the extent to which governmental authorities, private health insurers and other third-party payers provide coverage for and establish adequate reimbursement levels for our therapeutic product candidates. In the United States, the European Union and other potentially significant markets for our product candidates, government authorities and third-party payers are increasingly imposing more stringent requirements and restrictions on coverage, attempting to limit reimbursement levels or regulate the price of drugs and other medical products and services, particularly for new and innovative products and therapies, which often has resulted in average selling prices lower than they would otherwise be. For example, in the United States, federal and state governments reimburse covered prescription drugs at varying rates generally below average wholesale price. Federal programs also impose price controls through mandatory ceiling prices on purchases by federal agencies and federally funded hospitals and clinics and mandatory rebates on retail pharmacy prescriptions paid by Medicaid and Tricare. These restrictions and limitations influence the purchase of healthcare services and products. Legislative proposals to reform healthcare or reduce costs under government programs may result in lower reimbursement for our product candidates or exclusion of our product candidates from coverage. Moreover, the Medicare and Medicaid programs increasingly are used as models for how private payers and other governmental payers develop their coverage and reimbursement policies.

In addition, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and utilization, which may adversely affect any future product sales and our results of operations. These pressures can arise from rules and practices of managed care groups, competition within therapeutic classes, availability of generic equivalents, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, coverage and reimbursement policies and pricing in general. The cost containment measures that healthcare payers and providers are instituting and any healthcare reform implemented in the future could significantly reduce our revenues from the sale of any approved products. We cannot provide any assurances that we will be able to obtain and maintain third-party coverage or adequate reimbursement for our approved products in whole or in part.

Healthcare Reform

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs.

In recent years, Congress has considered reductions in Medicare reimbursement levels for drugs administered by physicians. Further, the Center for Medicare & Medicaid Services ("CMS"), the agency that administers the Medicare and Medicaid programs, also has authority to revise reimbursement rates and to implement coverage restrictions for some drugs. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products. While Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payers.

The Patient Protection and Affordable Care Act of 2010, as amended (the "Affordable Care Act" or "ACA"), substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The ACA was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms. Since its passage, there have been persistent efforts to modify or eliminate the ACA. These have, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers. These efforts are unlikely to abate in the near term, with new challenges to the individual mandate or to the ACA as a whole likely.

The Inflation Reduction Act of 2022, enacted on August 16, 2022 ("IRA"), includes several provisions to lower prescription drug costs for Medicare patients and reduce drug spending by the federal government, which could affect the pricing and reimbursement of our product candidates if they are approved for commercial sale. Pursuant to this, the CMS announced in August 2023 that it had selected the first ten drugs covered under Medicare Part D for negotiation, and selected an additional fifteen drugs for negotiation in January 2025. However, recent announcements from the second Trump administration call into question the administration's commitment to enforcing the IRA going forward, and CMS' drug pricing policies have engendered patent abuse lawsuits that call into question the limits of the government's pricing control efforts. It is unknown what this negotiation will yield or what form any future changes or any law would take, and how or whether it may affect our business in the future. We expect that changes or additions to the ACA, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry.

Payment methodologies may be subject to further changes in healthcare legislation and regulatory initiatives as well. In addition, at the state level, legislatures have passed and implemented, and may in the future pass and implement legislation and regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

The second Trump administration has granted the U.S. DOGE Service Temporary Organization, led by Elon Musk, broad discretionary authority to eliminate perceived inefficiency, fraud, waste, and abuse in government and to eliminate excessive regulation. It is unclear what effect these efforts at overhauling the federal administrative state will have on the administration or viability of federal healthcare programs and FDA and CMS' ability to oversee and administer these programs.

We expect that additional federal, state and foreign healthcare reform measures could be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

Exclusivity and Approval of Competing Products

Hatch-Waxman Patent Exclusivity

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's product or a method of using the product. Upon approval of a NDA, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application ("ANDA") or 505(b)(2) NDA. Generally, an ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths, dosage form and route of administration as the listed drug and has been shown to be bioequivalent through *in vitro* or *in vivo* testing or otherwise to the listed drug. ANDA applicants are not required to conduct or submit results of preclinical or clinical tests to prove the safety or effectiveness of their drug product, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug.

The ANDA or 505(b)(2) NDA applicant is required to provide a certification to the FDA in the product application concerning any patents listed for the approved product in the FDA's Orange Book, except for patents covering methods of use for which the applicant is not seeking approval. Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable, or will not be infringed by the new product.

Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except when the ANDA or 505(b)(2) NDA applicant challenges a listed patent or if the listed patent is a patented method of use for which approval is not being sought. A certification that the proposed product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV Certification. If the applicant does not challenge the listed patents or does not indicate that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA or 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of notice of the Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, a decision in the infringement case that is favorable to the ANDA applicant or other period determined by a court.

Hatch-Waxman Non-Patent Exclusivity

Market and data exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications for competing products. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of an NDA for a NCE. A drug is a NCE if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA, or supplement to an existing NDA or 505(b)(2) NDA, if new clinical investigations other than bioavailability studies that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application or supplement. Three-year exclusivity may be awarded for changes to a previously approved drug product, such as new indications, dosages, strengths or dosage forms of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and, as a general matter, does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Approval of Biosimilars and Biologic Exclusivity

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which was enacted as part of the ACA, created an abbreviated approval pathway for biological products that are demonstrated to be "biosimilar" or "interchangeable" with an FDA-licensed reference biological product via an approved BLA. 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 one or more clinical studies. Interchangeability, on the other hand, 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. Additionally, 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 abbreviated approval pathway remains challenging to implement, with many regulatory details still being refined by the FDA.

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. However, it remains uncertain whether FDA-approved interchangeable products will be readily substituted by pharmacies, as state pharmacy laws ultimately govern substitution practices.

Upon approval of a BLA, the biologic is listed by the FDA in its Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Purple Book, along with the date it was licensed; whether the FDA has determined that the licensed biological product is biosimilar to or interchangeable with a reference biological product (an already-licensed FDA biological product) and the date of expiration of applicable exclusivity. Under the BPCIA, a reference biologic is granted 12 years of exclusivity from the time of first licensure of the reference product. This 12-year period includes 4 years before the FDA may accept for filing an application for a biologic that references a branded (reference) product. The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate implementation and impact of the BCPIA is subject to significant uncertainty.

Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent exclusivity period described above. A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, 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 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 of a drug 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 generic 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 generic 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, 2024, we had twenty-three employees, all of whom were full-time. Thirteen 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 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 value diversity and inclusiveness at all levels.

Corporate Information

We were incorporated in Delaware in 2011 and commenced operations in the second quarter of 2011. Our principal executive offices are located at 540 Gaither Road, Suite 400, Rockville, Maryland 20850, 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.

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 cease our operations.

At December 31, 2024, we had $134.5 million in cash and cash equivalents and $7.0 million in current liabilities. As of the date of this Report, we believe we have sufficient funds to finance our continuing operations into at least 2027 to further advance our product candidates. However, 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.

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. Circumstances may cause us to consume or require capital more rapidly than we currently anticipate. As an example, our cash position in the past has caused us to prioritize product candidates for development, out-license certain product candidates and to defer the development of other candidates. We will need to raise additional funds or otherwise obtain funding through collaborations to complete the development of any of our product candidates and to continue our operations.

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. Furthermore, our ability to raise capital on a timely basis through the issuance and sale of equity securities might be limited by Nasdaq's listing rules on transactions that do not qualify as "public offerings" (as defined in Nasdaq listing rules), which might require us to obtain stockholder approval prior to the issuance of common stock (or securities convertible into or exercisable for common stock) at a price per share that is less than the "Minimum Price" if the issuance would equal 20% or more of our common stock outstanding before the issuance.

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 shareholders, 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 your position as a shareholder. 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 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.

If we do not raise additional capital when required or on acceptable terms, we may need to:

- Significantly delay, scale back or discontinue the development or commercialization of 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 ourself.

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 AVTX-009 and any future product candidates we may develop;
- The level of research and development investment required to develop product candidates;
- The rate and level of patient recruitment into clinical trials, including particularly the ongoing LOTUS Trial;
- 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 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 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 AVTX-009 or any future other product candidates;
- Our ability to promptly submit and secure approval 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;
- The effect of competing technological and market developments;
- 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 have incurred significant net losses in most periods since our inception and we expect to continue to incur net losses in the 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. Historically, we have financed our operations primarily through public and private equity offerings. We incurred a net loss of $35.1 million for the year ended December 31, 2024. As of December 31, 2024, we had an accumulated deficit of $370.3 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 our operations.

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 our ability to obtain approval of one or more of our product candidates to generate revenues. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We face risks associated with short-term liquid investments.

At December 31, 2024, we had $134.5 million in cash and cash equivalents. We historically have invested our cash in money market funds and intend to invest in a variety of 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, that 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 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.

Further, these types of investments are not insured against loss of principal, and cash and cash equivalents held in deposit accounts bear the risk of bank failure. 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 $183.0 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, 2024, the Company had various research tax credits of $6.3 million that will begin to expire in 2038. To the extent there is a limitation, there could be a reduction in the $7.0 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. 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 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.

Our role as a guarantor of certain obligations assigned to Aytu exposes us to risk of loss or illiquidity.

In connection with the Aytu Divestiture, as defined in the Notes to our Consolidated Financial Statements, we assigned payment obligations ("TRIS Obligations") to Aytu under a supply and distribution agreement (the "Karbinal Agreement") with TRIS Pharma Inc. ("TRIS"), which includes a per-unit royalty make whole payment for each unit sold under an annual minimum sales commitment through 2025. The total future make-whole payments to be made by Aytu are unknown as the amount owed to TRIS is dependent on the number of units sold.

As a part of the assignment, we became a guarantor to the TRIS Obligations. If Aytu defaults under the terms of the Karbinal Agreement, we could be liable as a guarantor for unpaid amounts of the TRIS Obligation. Any amount we would be required to pay under the TRIS Obligation would limit the amount of cash available for development of our clinical pipeline and may expose us to significant losses, which would materially and adversely affect our results of operations.

We have no approved commercial products.

Our supply and license agreement for our only commercial pharmaceutical product, Millipred®, which the Company considered a non-core asset, expired, as planned, on September 30, 2023. The product revenue from Millipred® was not sufficient to provide adequate capital for the continued development of our product candidates. 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 increase 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 AVTX-009, and our ongoing and anticipated clinical trials of AVTX-009 may not be successful.

Our future success relies heavily on our ability to successfully develop 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 AVTX-009. In October 2024 we announced the first patient enrolled in our global Phase 2 LOTUS clinical trial.

AVTX-009 will require further clinical development, assessment of clinical, preclinical, and manufacturing activities, regulatory approval in multiple jurisdictions, substantial investment, and significant marketing efforts before we can generate any revenue from product sales. We are not allowed to market or promote 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 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. Therefore, we cannot guarantee that we will ever generate revenue from the sale of AVTX-009, even if it receives regulatory approval. If we are unable to successfully commercialize AVTX-009, or if there are significant delays in doing so, our business will be materially impacted.

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 might 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 do not know whether the clinical trials we or our partners may conduct will demonstrate adequate efficacy and safety data resulting in regulatory approval enabling us to market any of our product candidates in any particular country. 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/or lead to insolvency of the Company.

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 AVTX-009 increases the risk of such exposure.

We have invested a significant portion of our efforts and financial resources in the identification and preclinical and clinical development of product candidates, including 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.

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.

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

- Delays in reaching an agreement with or failure in obtaining 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 agreements 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;
- Inability to agree with the FDA or other regulatory authorities on operationally viable endpoints or trial design;
- Imposition of a clinical hold or trial termination following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities, or due to concerns about trial design, or a decision by the FDA, other regulatory authorities, IRBs, ECs or us, or recommendation by a data safety monitoring board, to place the trial on hold or otherwise suspend or terminate clinical trials at any time for safety issues or for any other reason;
- Delays in reaching agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites;
- Deviations from the trial protocol by clinical trial sites and investigators, or failing 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;
- Failure to enter into agreements with third parties to obtain the results of clinical trials;
- 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 selected subjects;
- Delays due to the world-wide shortage of animal testing subjects, including monkeys;
- Delays in recruiting suitable 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 or disease progression;
- 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; or
- Changes in government regulations or administrative actions or lack of adequate funding to continue 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 subjects to participate in clinical trials of our product candidates, and retaining the subjects once qualified, is critical to our regulatory 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, 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, delays in testing the effectiveness of our technology or termination of the clinical trials altogether. Many factors affect subject enrollment, including:

- The size and nature of the subject population;
- The number and location of clinical sites we enroll;
- 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;
- Inability 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, and while we have agreements governing their committed activities, we have limited influence over their actual performance. 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 will 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.

Disruptions to the FDA, the SEC and other governmental agencies and regulatory authorities caused by funding shortages 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.

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 accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. 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.

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, in recent years, including 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. Additionally, action by the new Trump Administration to limit federal agency budgets or personnel may result in reductions to the FDA's budget, employees, and operations, which may lead to slower response times and longer review periods, potentially affecting 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. 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.

If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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 party clinical trials may cause us to be denied access to clinical results that may be significant to further clinical development.

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 product candidates may cause undesirable side effects or have other properties that could delay or prevent their marketing approval, limit the commercial profile of an approved label, 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 issue 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. 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 of these occurrences may harm our business, financial condition and prospects significantly.

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 development program, such as manufacturing methods and formulation, are altered in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the optimized materials. Such changes may also require additional testing, FDA or other regulatory authorities' notification or approval.

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 the conduct of 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.

Biologic 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, 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 highly 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 biologic 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.

Although we are working with third parties to develop reproducible and commercially viable manufacturing processes for our biologic 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-out, process reproducibility, stability issues, lot consistency, and timely availability of reagents or raw materials.

We may make changes as we continue to evolve the manufacturing processes for our biologic product candidates for advanced clinical trials and commercialization, and we cannot be sure that even minor changes in these processes will not cause our product candidates to perform differently and affect the results of our ongoing clinical trials, future clinical trials, or the performance of the product once commercialized. In some circumstances, changes in manufacturing operations, including to our protocols, processes, materials or facilities used, may require us to perform additional preclinical or comparability studies, or to collect additional clinical data from patients prior to undertaking additional clinical studies or filing for regulatory approval for a product candidate. These requirements might lead to delays in our clinical development and commercialization plans for our biologic product candidates and might increase our development costs substantially.

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.

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 and biotechnology companies worldwide. Many of our competitors have significantly greater financial, technical and human resources. 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 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.

There are now and could be future numerous approved therapies for treating the conditions our product candidates seek to address and, consequently, competition in these markets is intense. Many of these approved drugs are or may become well-established therapies or products and widely accepted by physicians, patients and third-party payors. Some of these drugs are or may become branded and subject to patent protection and non-patent regulatory exclusivity, and others are or may become available on a generic basis.

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;
- The ability to commercialize any of our product candidates that receive marketing approval;
- 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 candidate and might not become or remain profitable.

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 AVTX-009 increases the risk of such exposure.

Given our limited resources, we have prioritized certain product candidates over others at our management's discretion. 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. 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 no longer have the ability or resources to further develop other product candidates. 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 AVTX-009 increases the risk of this exposure.

Our focus and reliance on AVTX-009 exposes us to risk if AVTX-009 does not perform in clinical trials or receive FDA approval and market acceptance.

We acquired AVTX-009 in March 2024 and have focused our resources on AVTX-009 at the expense of allocating those resources to other assets. Consequently, our future financial condition and results of operations will primarily depend on AVTX-009. Any setback for or failure of 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 AVTX-009 or cease operations. In addition, our focus on 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 AVTX-009 as we continue its development. There can be no assurances that we will successfully develop AVTX-009.

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.

The time required to develop and to obtain approval from regulatory authorities to market a new drug is unique to each product. It typically takes many years in nonclinical and clinical development and depends upon numerous factors. 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. 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 (i.e., for new indications, dosing regimen, etc.) requires an application fee. 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.

Our product candidates could fail to receive regulatory approval from the FDA or a 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 support 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, specifically 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 required for a positive study;
- We may fail to demonstrate that a product candidate's benefits outweigh its risks;
- The FDA or other regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- Data collected from clinical trials of our product candidates may be insufficient to support the submission of a marketing application, other submission 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 precedence, 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. 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.

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, or an FDA Advisory Committee 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. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal 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.

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. 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.

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.

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. Since 2004, these False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements, such as settlements regarding certain sales practices promoting off-label drug uses involving significant fines. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid and other federal and state healthcare programs. 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. 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.

We are conducting clinical trials for 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 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. 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.

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 testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, 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. 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.

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 we obtain approval to commercialize our product candidates, the markets in which we will be selling are highly competitive and we might be unable to compete successfully against new entrants or established companies.

Competition in the pharmaceutical industry is intense and is characterized by costly sales and marketing infrastructures as well as extensive research efforts and rapid technological progress. We are aware of several pharmaceutical companies who commercially market products for the same condition or conditions we are targeting for AVTX-009. There may also be companies who are actively engaged in the development of therapies or products for at least some of these same conditions. Many of these companies have substantially greater research and development capabilities as well as substantially greater marketing, financial and human resources than we do. In addition, many of these companies have significantly greater experience than us in undertaking pre-clinical testing, clinical trials and other regulatory approval procedures. Our competitors may develop technologies and products that are more effective than those we are researching and developing. Such developments could render our product candidates, if approved, less competitive or possibly obsolete. We are also competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have no current capabilities and in which we have no experience as a company, even though our executive officers do have pharmaceutical commercialization and launch experience. Mergers, acquisitions, joint ventures and similar events may also significantly increase the competition we face. In addition, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical and medical technology industries at a rapid pace. These developments may render AVTX-009 or any of our product candidates obsolete or noncompetitive. Compared to us, many of our potential competitors have substantially greater capital resources as well as greater access to strategic partners. As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we can or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors might also develop products that are more effective, more useful and less costly than our products and might also be more successful in manufacturing and marketing their products. In addition, our competitors might be more effective in commercializing their products and as a result, our business and prospects might be materially harmed.

If we obtain approval to commercialize our product candidates outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If any of our product candidates are approved for commercialization, we may enter into agreements with third parties to market them on a worldwide basis or in more limited geographical regions. We expect that we would be subject to additional risks related to entering into international business relationships, including:

- Different regulatory requirements for approval, advertising and promotion of drugs in foreign countries;
- 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 United States;
- Foreign reimbursement, pricing and insurance regimes;
- Unexpected changes in tariffs, trade barriers and regulatory requirements;
- 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 currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- Foreign taxes;
- Difficulties staffing and managing foreign operations;
- Workforce uncertainty in countries where labor unrest is more common than in the United States;
- Potential liability under the FCPA or comparable foreign regulations;
- Production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- Business interruptions resulting from geopolitical actions, including war and terrorism, natural disasters, including earthquakes, typhoons, floods and fires, or pandemics.

These and other risks associated with any future international operations could materially adversely affect our ability to attain or maintain profitable operations.

Even if we commercialize any of our product candidates, these products may become subject to unfavorable third-party coverage and reimbursement policies, healthcare reform initiatives, or pricing regulations, any of which could negatively impact our business.

Our ability to commercialize any product candidates successfully will depend in part on the extent to which coverage and adequate reimbursement for these product candidates will be available from government authorities, private health insurers, health maintenance organizations and other entities. These third-party payors determine which medications they will cover and establish reimbursement levels, and increasingly attempt to control costs by limiting coverage and the amount of reimbursement for particular medications. Several third-party payors require drug companies to provide them with predetermined discounts from list prices, and use preferred drug lists to leverage greater discounts in competitive classes. In addition, federal programs impose penalties on drug manufacturers in certain instances, in the form of mandatory additional rebates and/or discounts, which can be substantial, and could impact our ability to raise commercial prices. We cannot be sure that coverage and reimbursement will be available for any product candidate that we commercialize and, if coverage is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or available only to limited levels, we might not successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or other regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates for a drug may vary according to the clinical setting in which it is used and may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Prices paid for a drug also vary depending on the class of trade. Prices charged to government customers are subject to price controls and private entities obtain discounts through group purchasing organizations. Net prices for drugs may be further reduced by mandatory discounts or rebates required by government healthcare programs and demanded by 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. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates and our overall financial condition.

Moreover, the regulations that govern pricing, coverage and reimbursement for new drug products abroad vary widely from country to country. Current and future U.S. or foreign legislation may significantly change the pricing, coverage and reimbursement in ways that could involve additional costs and cause delays in obtaining approvals. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates even if our product candidates obtain marketing approval.

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. We also maintain insurance coverage for our commercially available products, which might not adequately cover all liabilities that we may incur. 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.

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. 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.

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 third-party CROs to monitor and manage data for our clinical programs. We rely on these parties 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. 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, 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 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 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.

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.

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.

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.

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 an NDA or 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;
- 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;
- 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; and
- Failure to deliver our products under specified storage conditions and in a timely manner.

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. 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.

Our suppliers are subject to regulatory requirements covering manufacturing, testing, quality control, manufacturing, 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.

National and global health or geopolitical situations could have a negative adverse impact on our suppliers, which could impede the development or commercialization of our product candidates.

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 into 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.

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. 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;
- Collaborators might not perform their obligations as expected;
- The nonclinical studies and clinical trials conducted as part of these collaborations might not be successful;
- 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;
- 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;
- 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;
- 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;
- 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;
- 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;
- The terms of our collaboration agreement may restrict us from entering into certain relationships with other third parties, thereby limiting our 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.

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. 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. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

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;
- We may have to expend unexpected efforts and funds if we are unable to obtain the results of third-party clinical trials; and
- The competitiveness of any product candidate that is commercialized could be reduced.

Risks Related to Intellectual Property

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 our market. Furthermore, our patent for AVTX-009 is set to expire in 2026.

Our success depends in significant part on our and our licensors', licensees' or collaborators' ability to establish, maintain and protect patents and other intellectual property rights and operate without infringing the intellectual property rights of others. We have filed numerous patent applications both in the United States and in foreign jurisdictions to obtain patent rights to inventions we have discovered. We have also licensed from third parties' rights to patent portfolios.

The patent prosecution process is expensive and time-consuming, 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. 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. Therefore, these patents and applications might not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors, licensees or collaborators fail to establish, maintain or protect such patents and other intellectual property rights, such 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.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of 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 prevent others from commercializing competitive technologies and products. The patent examination process 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, 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 cover the technology.

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. We expect to seek extensions of patent terms where these are available in any countries where we are prosecuting patents. This includes in the United States under the 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. 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.

Our composition of matter patent for AVTX-009 expires in 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 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.

AVTX-009 is a biologic product, which would allow the Company to receive biologics reference product exclusivity in both the United States (twelve years) and Europe (ten years) if and upon receiving marketing approval for the products. Once our composition of matter patents expire, we plan to rely on such exclusivity to protect our intellectual property, 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.

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. The 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.

We believe that our current and any future product candidates we develop as biologic products should qualify for the 12-year period of 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 exclusivity, even if granted. Further, there is a risk that any exclusivity we receive is shortened due to Congressional action or otherwise, 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.

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 AVTX-009:

- The Lilly License Agreement; and
- The Leap Agreement

If we fail to comply with the obligations under these agreements, including payment terms, our licensors may have the right to terminate any 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.

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

We are party to license and development agreements with various third parties. For example, for our programs we are party to the Lilly License Agreement and the Leap Agreement. We may be required to make significant payments in connection with our license and development agreements including (but not limited to):

- Under the Lilly License Agreement, we will incur development costs for 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 AVTX-009, we are subject to additional sales-based milestones payable to Leap Therapeutics, Inc.; and
- For AVTX-009, we are subject to additional contingent development milestones 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.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, 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 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.

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 on 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 we 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 own or control. The 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 upon or misappropriating intellectual property rights we 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 an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or 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 narrowly.

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. An unfavorable outcome could require us or our licensors or collaborators to cease using the related technology and commercializing 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 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 proceeding, we may incur substantial costs and it may distract our management and other employees. We could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a 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.

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. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, 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 protect trade secrets. 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.

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 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 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.

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. 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 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 violation of our and our licensors' or collaborators' proprietary rights generally. Proceedings to enforce our and our licensors' or collaborators' patent rights in 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 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. This could limit our potential revenue opportunities. 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 Legal Compliance

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.

The Healthcare sector is heavily regulated in the United States and abroad. New laws, regulations, judicial decisions and/or payment and coverage policies—or new interpretations of such laws, regulations, decisions or policies—could negatively impact our business, operations, and financial condition. The United States federal government, state governments, and foreign governments have shown significant and increasing interest in cost-containment initiatives intended to limit the growth of healthcare costs, including without limitation price controls, restrictions on reimbursement, requirements for substitution of generic products for branded prescription drugs, prior authorization requirements, and increased copays and cost shares for beneficiaries.

The Patient Protection and Affordable Care Act increased federal oversight of private health insurance plans and included a number of provisions designed to reduce Medicare expenditures and the cost of health care generally, to reduce fraud, waste, abuse and to provide access to increased health coverage.

Since its enactment, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the Affordable Care Act that have resulted in profound changes to the law, and efforts to reform the ACA and healthcare sector are ongoing and are likely to gain momentum during the second Trump administration. Nevertheless, it is likely that any ongoing efforts to reform the financing and delivery of healthcare services in the United States will include the downward pressure on pharmaceutical pricing, especially under the Medicare program. Litigation and legislation related to these reforms are likely to continue, with unpredictable and uncertain results.

Some of these changes could have a material adverse effect on our business and operations. Ongoing and future healthcare reform measures may result, for instance, in more rigorous clinical coverage criteria limiting when our product(s) may be covered and in additional downward pressure on the price that we receive for our product and product candidates, if approved, and could harm our future revenues.

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of products approved for marketing in the United States by the FDA will depend, in part, on the extent to which products are covered by third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved.

Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, which are separate and apart from the costs required to obtain FDA or other comparable regulatory approvals based on the product's safety and effectiveness. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

In Europe and other countries outside of the United States, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed to. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. In some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

As stated above, the prices of prescription drugs have been the subject of considerable debate and regulation in the United States and abroad. Recent years have seen several U.S. congressional inquiries into prescription drug pricing, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare, and reform government program reimbursement methodologies for drugs and related products.

Efforts at cost containment in healthcare programs and related reforms are ongoing, with the new Trump administration promising to rollback or rescind many of the reforms and executive orders implemented under the Biden Administration. For example, President Biden signed an Executive Order on July 9, 2021, affirming the administration's policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs HHS to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations. It is unclear the extent to which any of these policies will continue under the new administration.

On August 16, 2022 the Inflation Reduction Act of 2022 was passed, which among other things, allows CMS to negotiate prices for certain single-source drugs and biologics reimbursed under Medicare Part B and Part D, beginning in 2026 with ten high-cost drugs paid for by Medicare Part D, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. The legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. The legislation also caps Medicare beneficiaries' annual out-of-pocket drug expenses at $2,000. The effect of the Inflation Reduction Act of 2022 on our business and the healthcare industry in general is not yet known. Further, the Trump Administration has frozen funding under the IRA, calling into question the law's continued viability in the new administration.

Future legislation and regulation is likely to result in further changes in Medicare and other healthcare funding, perhaps significantly, and to 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.

Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain and maintain profitability of our product and product candidates, if approved.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug formularies and other health care programs. These measures could reduce the ultimate demand for our product candidates, if approved, and/or may constrain the prices that we are able to charge for such products.

State and federal healthcare program reform measures are ongoing, any of which could limit the amounts that we receive for our product candidates, result in reduced demand for our product candidates, if approved.

Our relationships with commercial and government customers, healthcare providers, third-party payors, and others are subject to applicable anti-kickback, fraud and abuse, transparency and other healthcare related laws, regulations and requirements, which could expose us to criminal and civil liability, exclusion from participation in federal healthcare programs, contractual damages and consequences, reputational harm, administrative burdens, and diminished profits and future earnings.

Federal and state health care fraud and abuse laws and regulations apply to the healthcare providers and third-party payors who play a primary role in the recommendation and prescription of drug products. These laws constrain the business or financial arrangements and relationships through which we would market, sell, and distribute our product candidates and will impact, among other things, any of our future sales, marketing and educational programs. There are also laws, regulations, and requirements applicable to the award and performance of federal grants and contracts.

Our business operations and any current or future arrangements with third-party payors, healthcare providers and physicians may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we develop, market, sell and distribute any drugs for which we obtain marketing approval. In the United States, these laws include, without limitation, state and federal anti-kickback, false claims, physician transparency, and patient data privacy and security laws and regulations, including but not limited to those described below.

Actions resulting in violations of these laws regulations and requirements may result in civil and criminal liability, damages and restitution, as well as exclusion from participation in federal healthcare programs, corporate integrity agreements, deferred prosecution agreements, debarment from government contracts and grants and refusal of future orders under existing contracts or contractual damages, reputational damage, and other consequences. Restrictions under applicable federal and state healthcare related laws and regulations include but are not limited to the following:

- The federal Anti-Kickback Statute, which prohibits any person from, among other things, knowingly and willfully soliciting, offering, receiving or providing anything of value, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending purchase, lease or order, of any good or service for which payment may be made under a federal healthcare program;
- The Veterans Health Care Act, which requires manufacturers of covered drugs to offer them for sale on the Federal Supply Schedule and requires compliance with applicable federal procurement laws and regulations;
- The civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent;
- The false claims act, which imposes liability and significant civil penalties on any person who submits or causes to be submitted a claim to the federal government that he or she knows (or should know) is false;
- Federal transparency laws, including the federal Physician Sunshine Act (PSA), which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare and Medicaid Services, information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians (as defined above) and their immediate family members; and

- Analogous or similar state, federal, and foreign laws, regulations, and requirements which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; laws, regulations, and requirements applicable to the award and performance of federal contracts and grants and state, federal and foreign laws that govern the privacy and security of health and other information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal law, thus complicating compliance efforts.

The laws and regulations applicable to our business are complex, changing and often subject to varying interpretations. As a result, we may not be able to adhere to all applicable laws and regulations. Any violation or alleged violation of any of these laws or regulations by us could have a material adverse effect on our business, financial condition, cash flows and results of operations. We may be a party to various lawsuits, demands, claims, qui tam suits, third-party complaints to the FDA, government investigations and audits, of which any could result in, among other things, substantial financial penalties or awards against us, reputational harm, termination of relationships or contracts related to our business, mandated refunds, substantial payments made by us, required changes to our business practices, exclusion from future participation in Medicare and other healthcare programs and possible criminal penalties.

Compliance with these healthcare laws and regulations involves substantial costs. If a company is found to be in violation of any of these laws or any other laws, regulations or other requirements, it may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, restitution exclusion from government funded healthcare programs, corporate integrity agreements, deferred prosecution agreements, debarment from government contracts and grants and refusal of future orders under existing contracts, contractual damages, the curtailment or restructuring of our operations and other consequences.

The availability of any federal grant funds which we may receive or for which we may apply is subject to federal appropriations law. Such grant funding may also be withdrawn or denied due to a violation of the above laws and/or for other reasons or for no reason, as was recently demonstrated when the Trump administration unilaterally halted all payments under federal grants and loans.

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. Mittie Doyle, Chief Medical Officer, Dr. Garry A. Neil, Chief Executive Officer and Chairman of the Board, Jennifer Riley, Chief Strategy Officer, Christopher Sullivan, Chief Financial Officer, Paul Varki, Chief Legal Officer, Lisa Hegg Ph.D., Senior Vice President of Program Management and Corporate Infrastructure, Colleen Matkowski, Senior Vice President of Global Regulatory Affairs and Quality Assurance, and Dino Miano, Senior Vice President, CMC and Technical Operations, 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 AVTX-009. 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. For example, our executive management changed in February 2022. The loss of one or more of our executive officers or key associates could have a serious adverse effect on our business.

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 AVTX-009 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 man insurance with respect to any of such individuals.

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

In March 2024, we acquired AVTX-009 and AVTX-009 is currently the primary focus of our business. While we have experience with anti-inflammatory product candidates and AVTX-009 is an anti-inflammatory product candidate, we only have recently begun incorporating it into our operations. This could pose challenges to us in developing AVTX-009.

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 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. 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.

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. 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.

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.

Risks Related to our Stock

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.

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, and large spreads in bid and ask prices. 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.

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. 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. Broad market fluctuations and general economic and political conditions may also adversely affect the market price 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.

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. 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.

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. 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, 2024 is convertible into an aggregate of approximately 24.9 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, although the economic interest will not change because the value of shares issuable upon conversion was reflected in the purchase price of the preferred 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, 2024, there were 1,301,050 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, 2025, under these terms, an additional 1,768,393 shares were made available for issuance. In addition, as of December 31, 2024, there were 226,577 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, 2025, under these terms, the number of shares available for issuance under the ESPP increased by 353,679 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.

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.

Low trading volume of our common stock on the Nasdaq Capital Market may increase price volatility.

Our common stock may be subject to price volatility, low trading volume and large spreads in bid and ask prices quoted by market makers. Low trading means that trading in relatively small quantities may easily influence prices of our common stock. Low trading volume could also cause the price of our 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 trading volume. If large spreads between the bid and ask prices of our common stock exist at the time of a purchase, the stock would have to appreciate substantially on a relative percentage basis for an investor to recoup their investment. 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.

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. 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. 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, 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 or common stock equivalents would have on the market price of our common stock.

The non-voting convertible preferred stock outstanding at December 31, 2024 is convertible into an aggregate of approximately 24.9 million shares of our common stock, subject to certain beneficial ownership limitations. 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. 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.

In addition, in the future, we may also issue shares of our common stock in connection with investments or acquisitions. 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.

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. 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.

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.

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. 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. 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. 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.

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.

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. 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.

General Risk Factors

Our business and operations could suffer in the event of computer system 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 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 computer systems, 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, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Any such 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 our data being breached 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. Furthermore, as a result of cyber-attacks we may inadvertently misappropriate assets that we may not be able to fully recover.

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. 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 maintain a large quantity of sensitive information, including confidential business information and information associated with clinical trials. Because of the sensitivity of this information, our privacy and security measures related to such information are very important. Although we have privacy and security measures in place designed to protect 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 incidents, they 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), malfeasance, hacking, ransomware, social engineering (including phishing schemes), computer viruses, malware, or otherwise. 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 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. The harm associated with these negative results is likely to be exacerbated if the affected information is personally identifiable.

Like others in our industry, we experience cyber-attacks and other attempts to disrupt or gain unauthorized access to our systems on a regular basis. When we become aware of privacy or security incidents, we work diligently to address them, including by working to terminate unauthorized or inappropriate access and implementing additional measures, training, and providing guidance to end users in order to avoid the reoccurrence and future incidents. Although to date, privacy and security incidents have not been material, they could expose us to significant expense, legal liability, and harm to our reputation, which might result in an adverse impact our operating results.

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, there are 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 is subject to varying 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. The HHS Office for Civil Rights, which enforces HIPAA, 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. Privacy and data security has become an area of emphasis for some state legislatures, which have passed comprehensive state privacy laws, such as the California Consumer Privacy Act, the Colorado Privacy Act, and the Virginia Consumer Data Protection Act. 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. 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 and present challenges for our business model.

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 that 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, the General Data Protection Regulation ("GDPR") has imposed stringent obligations and restrictions on the ability to process and transfer personal information, including health data from clinical trials and substantial fines for breaches of the data protection rules in the European Economic Area ("EEA"). To the extent that our activities are or become subject to the GDPR, we may need to devote significant effort and resources to complying with those legal regimes. Any failure to comply with the rules arising from the 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 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 administrative fines of up to 4% of annual worldwide revenues. Fines of up to 2% of annual worldwide revenues can be levied for other specified violations. The validity of data transfer mechanisms remains subject to legal, regulatory, and political developments in both Europe and the United States, such as recent recommendations from the European Data Protection Board, the invalidation of the EU-U.S. Privacy Shield, and potential invalidation of other data transfer mechanisms, which could have a significant adverse impact on our ability to process and transfer personal data outside of the EEA. These developments create some uncertainty, and compliance obligations could cause us to incur costs or harm the operations of our products and services in ways that harm our business.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Avalo's management and Board of Directors recognize the importance of information security and managing cybersecurity risks across the enterprise. We have strategically designed our robust Information Security Program (the "Program") to assess, identify, and manage these cybersecurity risks, protect the Company from such risks, and respond to, and recover from, cybersecurity incidents.

The Company's Information Security Working Group ("ISWG") is actively engaged in managing cybersecurity risks and overseeing the design, implementation, and evaluation of the Program. The purpose of the ISWG is to define cybersecurity risk tolerance, guide implementation of the Program, monitor Program development and effectiveness, and validate investments in cybersecurity measures and infrastructure. Members of the ISWG include: the Chief Financial Officer, the Chief Legal Officer, the head of the Company's Human Resource department, the Senior Vice President of Program Management and Corporate Infrastructure, the Senior Vice President of Regulatory and Quality Assurance, and the Company's head of Information Technology. The group 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.

The Audit Committee (the "Committee") is primarily responsible for oversight of the Program. The Committee is composed of directors with expertise in technology, audit, finance, and compliance, equipping them to effectively oversee the program. Yingping Zhang serves as our Vice President of Information Technology, and she also helps oversee the implementation and effectiveness of the Program as a member of the ISWG. Ms. Zhang graduated from the University of Pittsburgh with a Master of Science in Electrical Engineering and has over thirty years of experience as an information technology professional. Prior to Avalo, Ms. Zhang worked as an Executive Consultant for Insightful Group, the Vice President of Information Technology at Horizon, and the Vice President of Informational Technology and Information Services at Viela Bio, among other positions within biopharma companies. Ms. Zhang reports to Lisa Hegg, Senior Vice President of Program Management and Corporate Infrastructure. Ms. Hegg provides information technology and cybersecurity reports as necessary at meetings of management's Disclosure Committee, which is communicated quarterly to the Audit Committee, with greater frequency as necessary. Ms. Zhang regularly informs Ms. Hegg, our Chief Executive Officer (CEO) and other members of the leadership team, about the Program, best practices, current cybersecurity threats, the 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 underlying controls of our Program are based on recognized best practices and standards for cybersecurity and information technology, including the National Institute of Standards and Technology (NIST) Cybersecurity Framework (CSF). Ms. Zhang is responsible for developing enterprise-wide cybersecurity strategy, architecture, policies, processes, and controls, and is directly responsible for our cybersecurity program.

We use various tools and methodologies to identify, manage, and test for cybersecurity risk on a regular cadence both at the enterprise level and using 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. To ensure we use reputable vendors for our information systems, we review and confirm SOC 1 reports for vendors providing critical business services. For vendors handling Avalo's clinical and manufacturing information, we employ quality agreements and vendor audits to ensure vendor compliance with our Program and all applicable regulatory requirements. We also engaged internal auditors to conduct a walkthrough of our information technology control environment, test our information technology controls, and report to us any findings. External security service firms monitor the Company's networks at all times, and Company laptops are patched weekly 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.

Our regular interactions with third-party vendors and suppliers pose a cybersecurity risk that could adversely impact our business or employees. We conduct information security assessments before onboarding and upon detection of an increase in risk profile. In addition, we require providers to meet appropriate security requirements, controls and responsibilities and include additional security and privacy addenda to our contracts where applicable.

Internally, our employees are a key part of our Program. All Avalo employees and contractors are required to participate in annual security awareness training, which includes phishing simulations. Company Employees are also trained on policies of information security and acceptable usage of systems, as well as procedures related to electronic record management, and Avalo regularly reviews and updates user accounts and permissions and ensures that only approved applications are installed on Company devices. The Company manages endpoints centrally and content can be deleted remotely in the event of stolen devices or terminated users.

To date, Avalo has not identified any cyber event or risks from cybersecurity threats that could be considered material, individually or in the aggregate. Notwithstanding our vigilance and our Program, we may not be successful in preventing or mitigating a cybersecurity incident that could have a material adverse effect on us. 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 Rockville, Maryland, where we occupy approximately 5,000 square feet of administrative office space. The lease expires on January 31, 2026.

The Company also occupies approximately 11,000 square feet of administrative office space in Chesterbrook, Pennsylvania. 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 17, 2025, there were approximately 149 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

Avalo Therapeutics, Inc. (the "Company," "Avalo" or "we") is a clinical stage biotechnology company focused on the treatment of immune dysregulation. Avalo's lead asset is AVTX-009, an anti-IL-1β monoclonal antibody ("mAb"), targeting inflammatory diseases.

Our initial focus in 2024 was augmenting our immunology pipeline and securing financing to develop our pipeline. In March 2024, we acquired our lead asset, AVTX-009, through our acquisition of AlmataBio, Inc. ("AlmataBio"). Concurrently, we executed a private placement of $185 million, including initial upfront investment of $115.6 million received in March 2024. We received the remaining $69.4 million of gross proceeds in the fourth quarter of 2024 upon the full exercise of the warrants issued as part of the transaction. Immediately following the acquisition of AVTX-009, our focus shifted to executing operationally on the development of AVTX-009 for the treatment of hidradenitis suppurativa ("HS"). This included activation of the Investigational New Drug ("IND") application in July 2024 and enrolling the first patient in our Phase 2 LOTUS trial in October 2024 (the "LOTUS Trial"). The LOTUS Trial is a global study designed to enroll 180 adults with HS to assess the efficacy and safety of convenient subcutaneous bi-weekly and monthly dosing regimens of AVTX-009, compared to placebo, with topline data expected in 2026.

Our focus in 2025 is continuing to execute operationally on the development of AVTX-009, most notably the progression of the LOTUS Trial. We are committed to executing the LOTUS Trial effectively and efficiently, as well as exploring AVTX-009's potential broad applications for other immune-mediated diseases as we work toward the announcement of our second indication.

Management's primary evaluation of Avalo's 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.

2024 Financial Operations Overview

As of December 31, 2024, Avalo had $134.5 million in cash and cash equivalents, representing a $127.1 million increase compared to December 31, 2023. During the year, we raised approximately $175.8 million of net proceeds from a private placement and the subsequent exercise of warrants issued in the private placement. Net cash used in operating activities were $49.1 million for the year ended December 31, 2024, which includes $12.5 million of milestone payments to AlmataBio pursuant to the terms of the acquisition in the first quarter. The Company's current cash on hand is expected to fund operations into at least 2027.

Net loss for the year ended December 31, 2024 was $35.1 million, representing a $3.6 million increase in net loss as compared to the prior year. Total operating expenses increased by $39.7 million, which was driven by the recognition of $27.6 million of acquired in-process research and development from the acquisition of AlmataBio in the first quarter of 2024, as well as a $10.7 million increase in research and development expenses and a $6.9 million increase in general and administrative expenses. Increased research and development expenses were driven by AVTX-009 development costs, including trial initiation and progression, as well as manufacturing, partially offset by limited development costs incurred in 2024 on other legacy programs. Increased general and administrative costs were driven by employee compensation costs, including stock-based compensation expense, as well as increased consulting, legal and other professional expenses following acquisition and financing that took place in the first quarter of 2024. Operating expense increases were partially offset by a $37.7 million increase to other income, primarily related to the warrants that were issued in 2024.

We expect future research and development expenses and cash used in operations, excluding the milestone payments made to the former AlmataBio stockholders, to increase in 2025 as a result of our development plans for AVTX-009, including the continued execution of the LOTUS Trial which commenced in October 2024.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

Product Revenue, net

The Company's license and supply agreement for Millipred® expired, as planned, on September 30, 2023. The Company continues to monitor estimates for commercial liabilities, such as sales returns. As additional information becomes available, the Company could recognize expense (or benefit) for differences between actuals or updated estimates to the reserves previously recognized. As such, the Company recognized $0.4 million in product revenue, net for the year ended December 31, 2024, compared to $1.4 million related to product sales for the year ended December 31, 2023. We do not expect future gross product revenue for Millipred®.

License and Other Revenue

Avalo recognized no license and other revenue for the year ended December 31, 2024. The Company recognized $0.5 million for the year ended December 31, 2023 as a result of the sale of its rights, title and interest in assets relating to the 800 Series (as defined in Note 4 to the consolidated financial statements) to AUG Therapeutics, LLC ("AUG").

Cost of Product Sales

We recognized a benefit of $0.4 million to cost of product sales for the year ended December 31, 2024, compared to cost of product sales of $1.3 million for the same period in 2023. The benefit recognized in the current period was mainly driven by the reversal of a $1.0 million reserve against the receivable due from Aytu BioScience, Inc. ("Aytu") in December 2024 given that Avalo expected the receivable to be collectible as of December 31, 2024, partially offset by additional royalty on the profit share as a result of a change in estimate for commercial liabilities. Avalo collected the receivable from Aytu in January 2025. The cost of product sales incurred in the prior period was driven by units sold.

The Company will continue to monitor estimates for commercial liabilities, such as sales returns and profit share with the supplier pursuant to the reconciliation process. 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, 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, 2024 and 2023:

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Nonclinical expenses	$ 570	$ 1,029
Clinical expenses	9,966	5,780
CMC expenses	5,106	1,855
Internal expenses:		
Salaries, benefits and related costs	6,164	3,576
Stock-based compensation expense	2,402	1,318
Other	229	226
	$ 24,437	$ 13,784

Research and development expenses increased $10.7 million for the year ended December 31, 2024, compared to the year ended December 31, 2023. Notably, clinical expenses increased $4.2 million in the current period due to LOTUS Trial activities including expenses incurred to activate the IND and trial initiation and execution expenses. Additionally, chemistry, manufacturing, and control ("CMC") expenses increased $3.3 million as a result of AVTX-009 raw material purchases and manufacturing. Clinical and CMC expense increases were partially offset by clinical development and manufacturing activity ongoing in the prior year for quisovalimab that did not repeat in the current year given the conclusion of the Phase 2 trial of quisovalimab in June 2023.

Salaries, benefits and related costs increased $2.6 million in the current period primarily due to increased non-equity incentive plan compensation expense incurred. Stock-based compensation expense increased $1.1 million due to option and restricted stock unit grants during the period, including the annual grant in August 2024.

We expect future research and development expenses to increase as a result of our development plans for AVTX-009, including the continued execution of the LOTUS Trial which commenced in October 2024.

Acquired in-process research and development

In the first quarter of 2024, we acquired AVTX-009 pursuant to the AlmataBio Transaction (as defined in Note 3 to the consolidated financial statements), resulting in us recording $27.6 million of acquired in-process research and development ("IPR&D"). We recognized the fair value of the IPR&D, substantially all of which is related to AVTX-009, for the year ended December 31, 2024 as there is no alternative future use. There was no acquired IPR&D for the year ended December 31, 2023.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the years ended December 31, 2024 and 2023:

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Salaries, benefits and related costs	$ 4,634	$ 2,340
Legal, consulting and other professional expenses	7,096	4,959
Stock-based compensation expense	3,450	2,157
Commercial planning and marketing expenses	789	33
Other	1,272	811
	$ 17,241	$ 10,300

General and administrative expenses increased $6.9 million for the year ended December 31, 2024, compared to the year ended December 31, 2023. The increase was driven by a $2.3 million increase in salaries, benefits and related costs due to increased non-equity incentive plan compensation expense, as well as a $1.3 million increase to stock-based compensation expense due to option and restricted stock unit grants during the period, including the annual grant in August 2024. In addition, legal, consulting and other professional expenses increased $2.1 million for accounting and reporting work incurred as well as increased consulting services following and largely related to the AlmataBio acquisition and March 2024 private placement. Commercial planning and marketing expenses increased $0.8 million due to work performed for HS and indication expansion, such as market opportunity assessments and competitive intelligence.

Although we expect the majority of our future operating expense increases will be focused on research and development activities to progress AVTX-009, we also expect moderate increases to general and administrative expenses to support the AVTX-009 program.

Goodwill Impairment

There was no goodwill impairment loss recognized for the year ended December 31, 2024. The Company recognized $3.9 million of goodwill impairment loss for its sole reporting unit for the year ended December 31, 2023 as part of its annual goodwill impairment test performed on the last day of the fiscal year. The impairment loss recognized represented the difference between the reporting unit's carrying value and its fair value as of December 31, 2023.

Other Income (Expense), net

The following table summarizes our other income (expense), net for the years ended December 31, 2024 and 2023:

	Year Ended December 31,	
	2024	2023
	(in thousands)	
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)	—
Change in fair value of derivative liability	(2,930)	(720)
Interest income (expense), net	3,317	(3,417)
Other expense, net	(5)	(42)
	$ 33,497	$ (4,179)

Other income, net increased $37.7 million for the year ended December 31, 2024 as compared to the prior period in 2023, primarily driven by the accounting impact of the warrant liability associated with the warrants issued in the March 2024 financing that were subsequently exercised in the fourth quarter of 2024. For the year ended December 31, 2024, we recognized a $79.3 million loss at issuance on the excess of initial warrant liability fair value ($194.9 million) over the private placement proceeds ($115.6 million). The loss was more than offset by a $121.6 million gain recognized on the change in fair value of the warrant liability from its initial valuation ($194.9 million) to the settlement of the warrant liability in the fourth quarter of 2024 ($73.3 million) upon the full exercise of the warrants. This gain was mainly driven by a decrease in the stock price from the initial valuation ($21.75 per share) to the stock prices on each warrant exercise date (weighted average of approximately $12.00 per share). Given the full exercise of the warrants in the fourth quarter of 2024, there was no warrant liability as of December 31, 2024, and we therefore do not expect related future activity in other income (expense), net. Refer to Note 6 - Fair Value Measurements of the consolidated financial statements for more information.

Additionally, interest income increased by $6.7 million contributing to the overall increase to other income, net. The increase was a result of the Company's increased cash position, paired with no interest expense in 2024 given the Company's full payoff of its loan in 2023.

The increase in other income, net was partially offset by a $2.9 million loss recognized on the increase in fair value of the derivative liability driven by changes in assumptions utilized in the valuation of both the AVTX-501 Milestone and the AVTX-007 Milestones and Royalties (as defined in Note 6 - Fair Value Measurements of the consolidated financial statements) due to updated publicly available information of the development plans for the assets by J&J and Apollo, respectively (as defined in Note 6 to the consolidated financial statements). Refer to Note 6 - Fair Value Measurements of the consolidated financial statements for more information. The overall increase to other income, net was also partially offset by $9.2 million of private placement transaction costs, largely consisting of the private placement agent fee of $7.0 million due in March 2024 and $1.7 million due on the exercise of the warrants.

Income Tax Expense

The following table summarizes our income tax expense for the years ended December 31, 2024 and 2023:

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Income tax expense	$ 114	$ 14

The Company recognized minimal income tax expense for the years ended December 31, 2024 and 2023.

Liquidity and Capital Resources, including Capital Expenditure and Cash Requirements

Since inception, we have incurred significant operating and cash losses from 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, 2024, Avalo generated a net loss of $35.1 million and negative cash flows from operations of $49.1 million. As of December 31, 2024, Avalo had $134.5 million in cash and cash equivalents. For the year ended December 31, 2024, the Company raised approximately $175.8 million of net proceeds from a private placement and the subsequent exercise of warrants issued in the private placement.

Based on our current operating plans, we expect that our existing cash and cash equivalents are sufficient to fund operations into at least 2027. 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.

Uses of Liquidity

The Company primarily uses cash to fund the ongoing development of our research and development pipeline assets and costs associated with its organizational infrastructure. As of December 31, 2024, Avalo had $134.5 million in cash and cash equivalents, representing a $127.1 million increase compared to December 31, 2023. We expect cash used in operating activities, excluding the milestone payments made to the former AlmataBio stockholders, to increase in future periods as a result of our development plans for AVTX-009, including the execution of the LOTUS Trial which commenced in October 2024.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2024 and 2023:

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Net cash provided (used in) by:		
Operating activities	$ (49,056)	$ (30,680)
Investing activities	356	(133)
Financing activities	175,849	25,042
Net increase (decrease) in cash and cash equivalents	$ 127,149	$ (5,771)

Net cash used in operating activities

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 AVTX-009.

Net cash used in operating activities in 2023 consisted primarily of a net loss of $31.5 million and non-cash adjustments to reconcile net loss to net cash used in operating activities, including goodwill impairment of $3.9 million, stock-based compensation of $3.5 million, accretion of debt discount of $1.8 million, and increase in fair value of the derivative liability of $0.7 million. Accrued expenses and accounts payable decreased an aggregate of $11.5 million from December 31, 2022.

We expect cash used in operating activities, excluding the milestone payments made to the former AlmataBio stockholders, to increase in future periods as a result of our development plans for AVTX-009, including the continued execution of the LOTUS Trial which commenced in October 2024.

Net cash provided by (used in) investing activities

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 used in investing activities was minimal for the year ended December 31, 2023.

Net cash provided by financing activities

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.

Net cash provided by financing activities for the year ended December 31, 2023 consisted of net proceeds of $46.2 million from equity financings, partially offset by debt principal payments of $21.2 million, inclusive of the full payoff of the loan in September of 2023. Avalo fully retired its debt in 2023.

Critical Accounting Estimates and Assumptions

In preparing the financial statements, the Company makes 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. The Company believes, 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

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 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, 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 life 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 as opposed to being estimated at the time of grant and revised.

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	**2024**			**2023**		
Expected term of options (in years)	5.81	—	6.25	5.00	—	6.25
Expected stock price volatility	113.1%	—	116.9%	89.8%	—	146.0%
Risk-free interest rate	3.70%	—	4.26%	3.43%	—	4.13%
Expected annual dividend yield	0%			0%		

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. We recognize compensation expense for only the portion of awards that are expected to vest.

Warrant Liability

On March 28, 2024, the Company closed a private placement in which the investors received (i) 19,946 shares of 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 is then exercisable into) with an exercise price of $5.796933. Refer to Note 11 - Capital Structure and sub-header "March 2024 Financing" of the consolidated financial statements 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, 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 including the value of the stock on the measurement date, exercise price, expected term, expected volatility, and the risk-free interest rate. Certain assumptions, including the expected term and expected volatility, were subjective and required judgment. 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. Upon exercise of the warrants in the fourth quarter of 2024, the final fair value of the warrant liability was $73.3 million. Given the full exercise of the warrants, there was no warrant liability as of December 31, 2024, resulting in the $121.6 million gain on the change in fair value recognized in other income (expense), net in the accompanying consolidated financial statements of operations and comprehensive loss for the year ended December 31, 2024. Refer to Note 11 - Capital Structure of the consolidated financial statements for additional discussion regarding the issuance of the Series C Preferred Stock and common stock pursuant to the warrant exercises.

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 Master Fund Ltd. (an affiliate of Armistice Capital, LLC, and collectively "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 Pharmaceuticals, 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, including up to $6.25 million of development milestones, up to $67.5 million in sales-based milestones, and royalty payments 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 include 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, all of which 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 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 AVX-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, 2024, the fair value of the derivative liability was $8.5 million, all of which was attributable to the AVTX-007 Milestones and Royalties and $0.4 million of which was classified as a current liability with the remainder classified as a non-current liability as of December 31, 2024. For the year ended December 31, 2024, the $2.9 million loss on the change in fair value was recognized in other income (expense), net in the accompanying consolidated statements of operations and comprehensive loss.

The fair value of the AVTX-501 Milestone was deemed to be $0.0 million, driven by less than 1% probability of success based on Avalo's interpretation of a recent announcement from J&J noting the discontinuation of the aticaprant depression program (previously referred to as AVTX-501 by Avalo), which was the only indication that we are aware they were pursuing, 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 $1.8 billion in atopic dermatitis, which is a much larger market opportunity than adult-onset Still's disease (the previous indication being pursued that was contemplated in valuations through the first quarter of 2024), an approximate 17% probability of success, and an estimated time to commercialization of approximately 6.0 years. 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 the fair value.

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.

Asset Acquisition

To evaluate a transaction to assess whether or not the transaction should be accounted for as a business combination or asset acquisition, the Company first applies 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 is met, the transaction is accounted for as an asset acquisition. If the screen 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.

In the first quarter of 2024, we acquired AVTX-009, through a merger with AlmataBio and its wholly owned subsidiary, resulting in us acquiring $27.6 million of IPR&D. The fair value of the IPR&D, substantially all of which is related to AVTX-009, was immediately recognized as acquired IPR&D expense as there is no alternative future use.

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.

Off-Balance Sheet Arrangements

The Company does 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, 2024, 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, 2024.

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, 2024, 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, 2024.

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.

Trading Arrangements

During the quarter ended December 31, 2024, none of our directors or officers (as defined in rule 16a-1(f) under the Exchange Act) adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement" (as such terms are defined in Item 408 of Regulation S-K).

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 seven 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
Garry Neil, M.D.	71	June 2022	Chairman of the Board of Directors, President, Chief Executive Officer
June Almenoff, M.D., Ph.D.	68	November 2021	Director
Mitchell Chan	44	December 2021	Director
Jonathan Goldman, M.D.	60	March 2024	Director
Aaron Kantoff	39	March 2024	Director
Gilla Kaplan, Ph.D.	78	October 2020	Director
Samantha Truex	54	March 2024	Director

The following is a brief biography of each current director:

Garry Neil, M.D. Dr. Neil has served as the President and Chief Executive Officer of the Company since February 2022. Dr. Neil was appointed to our Board on June 14, 2022 and was appointed Chairman of our Board on August 8, 2022. From March 2020 to February 2022, Dr. Neil served as the Chief Scientific Officer of Avalo. 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. Dr. Neil also serves on the board of Celldex Therapeutics, Inc. (Nasdaq: CLDX). Dr. Neil served on the board of directors of Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) until it was acquired by Pfizer Inc. (NYSE: PFE) in March 2022. Dr. Neil previously served as a member of the board of directors of Zura Bio Ltd. (Nasdaq: ZURA) and GTx, Inc. (previously Nasdaq: GTXI). Dr. Neil also serves on the Board of Directors of the Reagan Udall Foundation and the Center for Discovery and Innovation. 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.

June Almenoff, M.D., Ph.D. Dr. Almenoff has served on our Board since November 2021. She is an accomplished biopharma executive with 25 years of senior leadership experience. She currently serves as a Board Director and advisor to management of numerous biopharma companies. Dr. Almenoff previously served, from March 2010 to October 2014, as President and Chief Medical Officer and a member of the board of directors of Furiex Pharmaceuticals, Inc. (previously Nasdaq: FURX) ("Furiex"), which was acquired by Actavis plc (now AbbVie, Inc.) for $1.2 billion in July 2014. Furiex developed eluxadoline (Viberzi®), which was approved both in the United States and Europe. Prior to joining Furiex, Dr. Almenoff also served as Chief Medical Officer of RedHill Biopharma Ltd (Nasdaq: RDHL) leading a team that was instrumental in positioning Talicia® as a first-line therapy.

Earlier in her career, Dr. Almenoff was at GlaxoSmithKline plc (NYSE: GSK) for twelve years, where she held various positions of increasing responsibility, including most recently Vice President in the Clinical Safety organization. While at GlaxoSmithKline, Dr. Almenoff also chaired a PhRMA-FDA working group, and worked in the area of scientific licensing. She also led the development of pioneering data analytics systems, which have been widely adopted by industry regulators to minimize clinical risk for both development and marketed drugs. Dr. Almenoff is currently a member of the investment advisory board of the Harrington Discovery Institute (a venture philanthropy) and an Executive Venture Partner (part-time) at 82 Venture Studios (affiliated with Alloy Therapeutics). She has served as independent Board Director of Tenax Therapeutics, Inc. (Nasdaq: TENX) since 2021 and Actinium Pharmaceuticals, Inc. (NYSE: ATNM) since 2024. She previously served as a member of the board of directors of Brainstorm Therapeutics, Inc. (Nasdaq: BCLI) from 2017 to 2023, Tigenix NV (acquired by Takeda Pharmaceutical Company Limited in August 2018) from 2016 to 2018, and Kurome Therapeutics, Inc. from 2020 to 2021. Dr. Almenoff has strong expertise in translational medicine, clinical development, commercial strategy, and business development across many therapeutic areas. She has led or contributed to numerous regulatory submissions, product approvals and launches. Dr. Almenoff received her B.A. cum laude from Smith College and graduated with AOA honors from the M.D.-Ph.D. program at the Icahn (Mt. Sinai) School of Medicine. She completed post-graduate medical training at Stanford University Medical Center and served on the faculty of Duke University School of Medicine. She is an adjunct Professor at Duke, a Fellow of the American College of Physicians (FACP) and has authored over 70 publications. Our Board believes that Dr. Almenoff's 25 years of leadership experience as a biopharma executive, her expertise in research and development, as well as her experience with biotech boards, venture philanthropy investment, and product commercialization makes her 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 March 2021, Mr. Chan was at Viela Bio, Inc. ("Viela"), a clinical-stage biotechnology company, and most recently served as the Chief Financial Officer and oversaw the acquisition of Viela by Horizon Therapeutics plc for $3.1 billion. 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 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 more than 15 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. He currently serves as the CEO of Clinical ink, a global life science company that brings data, technology, and patient-centric research together. Prior to Clinical ink, Dr. Goldman served as the CEO and a board member of Abzena Limited 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.

Aaron Kantoff. Mr. Kantoff has served on our Board since March 2024. Mr. Kantoff is currently co-founder and managing partner of Scion Life Sciences, which is affiliated with Petrichor Healthcare Capital Management LP. Since April 2022, 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 September 2023. Mr. Kantoff served as a venture partner of Medicxi Ventures (UK) LLP, an investment firm focused on the life sciences sector, where he served on the board of directors of Centessa Pharmaceuticals plc (Nasdaq: CNTA) from January 2021 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. (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 currently serves as the Chief Research Officer of Gilrose Pharmaceuticals. She 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.

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, including the last five years in CEO roles. Since June 2022, Ms. Truex has served on the board of Artios Pharma Limited and has previously served on the boards of Hotspot Therapeutics, Inc., iPierian, Inc. (acquired by Bristol Myers Squibb) and True North Therapeutics (acquired by Bioverativ Inc.). Ms. Truex was the founding CEO of Upstream Bio, Inc., from October 2021 to March 2024, and the CEO of Quench Bio, Inc. from August 2018 to March 2021. Ms. Truex was previously the COO of Synlogic Therapeutics and CBO for Padlock Therapeutics, Inc. 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. 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 also chairs 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, make 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.	71	Chairman of the Board of Directors, President, Chief Executive Officer
Mittie Doyle, M.D., FACR	60	Chief Medical Officer
Jennifer Riley	50	Chief Strategy Officer
Christopher Sullivan	41	Chief Financial Officer
Paul Varki	52	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.

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, 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 (August 2016 to October 2017), Vice President, Clinical Research, Flexion Therapeutics (April 2015 to August 2016) and Senior Medical Director at Alexion Pharmaceuticals (June 2012 to April 20215). Dr. Doyle currently serves on the Board of Directors of Santa Ana Bio. She also served on the Board of Directors of DICE Therapeutics ("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. Most recently, in October of 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. 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 (2007 to 2009), where she built the team and established the organizational model for the new business area, and Director of Operations (2007), where she oversaw the integration activities following the acquisition of Syntonix Pharmaceutics 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 to Chief Financial Officer, Mr. Sullivan served as Chief Accounting Officer of the Company since March 2021. 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 for $1.2 billion. 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 both Braeburn Pharmaceuticals, (September 2017 to November 2018) and as Egalet Pharmaceuticals (November 2015 to August 2017). 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. Mr. Varki also practiced FDA regulatory law at Reed Smith LLP and has served as Regulatory Counsel at the Center for Drug Evaluation and Research at the FDA. 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*.

Additionally, our insider trading policy 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.

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. Chan (Chair), Dr. Almenoff and Dr. Goldman.

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. Chan qualifies as an "audit committee financial expert," as defined in applicable SEC rules. The Board made qualitative assessments of Mr. Chan's level of knowledge and experience based on a number of factors, including formal education and experience.

The Audit Committee met five times during 2024. 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*.

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, 2024, 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, 2024 and 2023, 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, 2024 (the "Named Executive Officers"). Our Chief Executive Officer and Chief Financial Officer were the only executive officers who served during the year ended December 31, 2023.

Name and Principal Position	Year	Salary	Non-Equity Incentive Plan Compensation[1]	Option Awards[2]	Stock Awards[2]	All Other Compensation	Total
Garry Neil, M.D. *Chief Executive Officer, President, Chairman of the Board and principal executive officer*	2024	$532,500	$501,800	$4,255,801	$1,922,648	$—	$7,212,749
	2023	$475,000	$166,250	$434,112	$—	$—	$1,075,362
Mittie Doyle *Chief Medical Officer*	2024	$231,061	$216,000	$2,586,696	$—	$—	$3,033,757
	2023	$—	$—	$—	$—	$—	$—
Christopher Sullivan *Chief Financial Officer and principal financial officer*	2024	$400,000	$229,400	$1,587,846	$717,288	$—	$2,934,534
	2023	$350,000	$84,000	$173,645	$—	$—	$607,645

(1) The amounts reflect the discretionary 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, as well as a retention bonus paid to Dr. Neil and Mr. Sullivan in 2024. The annual bonus is typically paid in the year following the year it was earned.

(2) The amounts reflect the grant date fair value for option and restricted stock unit awards, respectively, granted during 2024 and 2023 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, 2024. 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.

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 2024, as determined by the Compensation Committee.

Name	2024 Base Salary	
Garry Neil, M.D.	$590,000	(1)
Mittie Doyle, M.D., FACR	$500,000	(2)
Christopher Sullivan	$450,000	(3)

(1) Reflects base salary increase from $475,000, effective as of June 30, 2024.

(2) Reflects non-prorated base salary upon employment in July 2024.

(3) Reflects base salary increase from $350,000, effective as of June 30, 2024.

Annual Bonus

Our discretionary 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 discretionary 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. As recommended by the Compensation Committee and approved by the Board, our Named Executive Officers will receive a bonus relative to achievement of goals for fiscal year 2024 provided they are employed on the date such annual bonus is paid. In accordance with her employment agreement, the annual bonus for Dr. Doyle related to fiscal year 2024, her first year of employment, was not prorated based on her start date and was paid at the full percentage of her base salary. Both Dr. Neil and Mr. Sullivan received retention bonuses in February 2024 in the amounts of $47.5 thousand and $35.0 thousand, respectively.

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 most recently in August 2019 with the approval of our Board of Directors 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.

2023 Reverse Stock Split

On December 28, 2023, Avalo effected a 1-for-240 reverse stock split of the outstanding shares of the Company's common stock and began trading on a split-adjusted basis on December 29, 2023. The Company retroactively applied the reverse stock split to common share and per share amounts for periods prior to December 28, 2023. Additionally, pursuant to their terms, a proportionate adjustment was made to the per share exercise price and number of shares issuable under all of the Company's outstanding options and warrants, and the number of shares authorized for issuance pursuant to the Company's equity incentive plans have been reduced proportionately. Avalo retroactively applied such adjustments within this Annual Report on Form 10-K for periods presented prior to December 28, 2023. The reverse stock split did not reduce the number of authorized shares of common and preferred stock and did not alter the par value.

Other Compensation

Our Named Executive Officers did not participate in, or otherwise receive any benefits under, any pension or deferred compensation plan sponsored by the Company during fiscal year 2024 or fiscal year 2023. We generally do not provide perquisites or personal benefits to our Named Executive Officers.

Employment Agreements and Potential Payments Upon Certain Events

Garry Neil, M.D.

In connection with Dr. Neil's appointment as President and Chief Executive Officer, the Company and Dr. Neil entered into a letter agreement dated February 18, 2022 (the "Neil Letter Agreement"), which modified his previously filed employment agreement dated January 30, 2020 (collectively with the Neil Letter Agreement, the "Neil Employment Agreement"). Pursuant to the Neil Letter Agreement, Dr. Neil's base salary was increased to $475,000 per year, subject to review and adjustment by the Board from time to time (the Board adjusted Dr. Neil's base salary to $590,000 effective July 1, 2024). He 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, with a target amount of up to seventy percent (70%) of his base salary, and conditioned on Dr. Neil being employed by the Company on the applicable bonus payment date. Such annual discretionary bonus may be paid, in Dr. Neil'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. Pursuant to the Neil Letter Agreement, Dr. Neil was also granted a stock option on March 8, 2022 to purchase 348 shares of the Company's common stock, vesting over four years, with a 12-month cliff, such that the first 25% vested on the first anniversary of such grant, and the remainder will vest in equal monthly installments over the following three years, in each case, subject to continued employment with the Company through the applicable vesting date. Dr. Neil 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.

Pursuant to the Neil Employment Agreement, Dr. Neil was granted an inducement grant of non-qualified stock options in accordance with Nasdaq Listing Rule 5635(c)(4) to purchase 278 shares of common stock. The inducement option grant will vest over four years, with the first 25% of such options vesting on the grant date's first anniversary, and the remainder vesting in equal monthly installments, provided that Dr. Neil remains an employee of the Company as of each such vesting date.

Dr. Neil's employment agreement prohibits the disclosure or use of any proprietary or confidential information obtained by him as a result of his employment with the Company. Dr. Neil is obligated not to compete with the Company during his employment and for a period of one year following his termination of employment with the Company. In addition, his 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

Pursuant to the Neil 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 each of 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 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.

Mittie Doyle, M.D., FACR

In connection with Dr. Doyle's appointment as Chief Medical Officer, the Company and Dr. Doyle entered into an employment agreement dated June 1, 2024 (the "Doyle Employment Agreement").
Pursuant to the Doyle Employment Agreement, the Company has agreed to provide Dr. Doyle with a base salary of $500,000, subject to annual review beginning in 2025, and she is eligible to receive a discretionary annual bonus as determined by the Board or the Compensation Committee of the Board, in its sole discretion, with a target amount of up to forty percent (40%) of her base salary, and conditioned on Dr. Doyle being employed by the Company on the applicable bonus payment date. Such annual discretionary bonus may be paid in the form of cash, or if mutually agreeable, equity award (which for 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.

Pursuant to the Doyle Employment Agreement, on July 15, 2024, Dr. Doyle was granted an inducement grant of non-qualified stock options in accordance with Nasdaq Listing Rule 5635(c)(4) to purchase 234,000 shares of the Company's common stock, vesting over four years, with a 12-month cliff, such that the first 25% will vest on the first anniversary of such grant, and the remainder will vest in equal monthly installments over the following three years, in each case, subject to continued employment with the Company through the applicable vesting date. Dr. Doyle is also eligible to participate in the Company's other employee benefit plans in effect from time to time on the same terms as generally available to the Company's other senior executives.

Dr. Doyle's employment agreement prohibits the disclosure or use of any proprietary or confidential information obtained by her as a result of her employment with the Company. Dr. Doyle is obligated not to compete with the Company during her employment and for a period of one year following her termination of employment with the Company. In addition, her 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

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

(i) certain "Accrued Benefits" (as defined in the Doyle 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 her base salary as in effect immediately prior to her termination for nine consecutive months following such termination (extended to twelve months if Dr. Doyle's termination occurs within six months following a Change in Control, as defined in the Doyle 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, 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 she will have six months from the date of her termination in which to exercise her options; and
(vi) if she timely elects and remains eligible for continued coverage under federal COBRA law or, if applicable, state insurance laws, the Company will pay Dr. Doyle's COBRA or state continuation health insurance premiums until the earliest of (x) the first anniversary of her termination, (y) expiration of her continuation coverage under COBRA, or (z) the date when she 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)-(iv) shall be made promptly after its closing or termination, whichever is later.

Christopher Sullivan

In connection with Mr. Sullivan's appointment as Chief Financial Officer, the Company and Mr. Sullivan entered into a letter agreement dated February 18, 2022 (the "Sullivan Letter Agreement"), which modifies his previously filed employment agreement dated September 26, 2019, as amended by a previously filed letter agreement dated April 23, 2020 (collectively with the Sullivan Letter Agreement, the "Sullivan Employment Agreement"). Pursuant to the Sullivan Letter Agreement, Mr. Sullivan's base salary was increased to $350,000 per year, subject to review and adjustment by the Board from time to time (the Board adjusted Mr. Sullivan's base salary to $450,000 effective July 1, 2024). He 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, with a target amount of up to forty percent (40%) of his base salary, and conditioned on Mr. Sullivan being employed by the Company on the applicable bonus payment date.

Such annual discretionary bonus may be paid, in Mr. Sullivan's discretion, in the form of cash or equity award (which for 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. Mr. Sullivan received a appointment bonus of $50,000.

Pursuant to the Sullivan Letter Agreement, Mr. Sullivan was granted a stock option on March 8, 2022 to purchase 140 shares of the Company's common stock, vesting over four years, with a 12-month cliff, such that the first 25% will vest on the first anniversary of such grant, and the remainder will vest in equal monthly installments over the following three years, in each case, subject to continued employment with the Company through the applicable vesting date. Mr. Sullivan 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.

Mr. Sullivan's employment agreement prohibits the disclosure or use of any proprietary or confidential information obtained by him as a result of his employment with the Company. Mr. Sullivan is obligated not to compete with the Company during his employment and for a period of six months following his termination of employment with the Company. In addition, his 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

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

(i) certain "Accrued Benefits" (as defined in his 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 twelve 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 each 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 termination, whichever is later.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

The following table shows for the fiscal year ended December 31, 2024, certain information regarding outstanding equity awards at fiscal year-end for each of the Named Executive Officers.

Name	Grant Date	Award Type	Unvested Restricted Stock Units (#)	Unexercised Options Exercisable (#)	Unexercised Options Unexercisable (#)	Option Exercise Price ($)	Option Expiration Date
Garry Neil, M.D.	2/3/2020	Stock Option[1]	—	278	—	$ 11,462.40	2/3/2030
	1/26/2021	Stock Option[1]	—	90	2	$ 9,561.60	1/26/2031
	3/8/2022	Stock Option[1]	—	240	108	$ 2,016.00	3/8/2032
	10/5/2022	Stock Option[2]	—	313	—	$ 952.80	10/5/2032
	2/13/2023	Stock Option[1]	—	191	227	$ 715.20	2/13/2033
	5/15/2023	Stock Option[2]	—	417	—	$ 660.00	5/15/2033
	8/13/2024	Stock Option[3]	—	—	500,400	$ 9.88	8/13/2034
	8/13/2024	Restricted Stock Unit[4]	194,600	—	—	$ —	—
Mittie Doyle, M.D., FACR	7/15/2024	Stock Option[1]	—	—	234,000	$ 12.65	7/15/2034
Christopher Sullivan	5/1/2018	Stock Option[1]	—	14	—	$ 11,174.40	5/1/2028
	4/1/2019	Stock Option[1]	—	18	—	$ 17,913.60	4/1/2029
	4/9/2020	Stock Option[1]	—	32	—	$ 7,401.60	4/9/2030
	1/26/2021	Stock Option[1]	—	39	—	$ 9,561.60	1/26/2031
	3/8/2022	Stock Option[1]	—	96	44	$ 2,016.00	3/8/2032
	3/8/2022	Stock Option[2]	—	18	—	$ 2,016.00	3/8/2032
	10/5/2022	Stock Option[2]	—	105	—	$ 952.80	10/5/2032
	2/13/2023	Stock Option[1]	—	78	89	$ 715.20	2/13/2033
	5/15/2023	Stock Option[2]	—	167	—	$ 660.00	5/15/2033
	8/13/2024	Stock Option[3]	—	—	186,700	$ 9.88	8/13/2034
	8/13/2024	Restricted Stock Unit[4]	72,600	—	—	$ —	—

(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 shall vest 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 awards will vest in three equal installments on each of March 28, 2025, March 28, 2026, and March 28, 2027.

DIRECTOR COMPENSATION

After consultation with an independent compensation consultant, our Board approved a compensation policy for our non-employee directors that became effective upon the closing of our initial public offering (the "Compensation Policy"). The Compensation Policy was most recently amended on June 6, 2024 with an effective date of July 1, 2024 after consultation with an independent, external compensation consultant, Radford, an Aon Company. The Compensation Policy provided for the following compensation to our non-employee directors effective July 1, 2024, with the prior amounts effective in 2023 and through June 30, 2024 indicated below in parenthesis:

- The chair of our Board (if not an employee director) receives an annual fee of $70,000 (also previously $70,000) and each other non-employee director receives $40,000 (also previously $40,000);

- The chair of our Audit Committee receives an annual fee of $20,000 (previously $15,000) and each other member receives $10,000 (previously $7,500);
- The chair of our Compensation Committee receives an annual fee of $13,000 (previously $10,000) and each other member receives $6,500 (previously $5,000);
- The chair of our Nominating and Corporate Governance Committee receives an annual fee of $10,000 (previously $8,000) and each other member receives $5,000 (previously $4,000);
- The chair of our Science and Technology Advisory Committee receives an annual fee of $15,000 (also previously $15,000) and each other member receives $7,500 (also previously $7,500); and
- Each non-employee director is entitled to an initial grant of stock options to purchase 34,100 shares of our common stock (previously 28) that vests in three substantially equal annual installments over three years commencing on the first anniversary of the grant date.
- Beginning in 2025, on the date of each annual stockholders meeting of the Company, each non-employee director is entitled to an annual grant of stock options to purchase 17,050 shares that 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.
- Per the Compensation Policy amendment effective July 1, 2024, in 2024 only, on the date of the first annual stockholders meeting of the Company after the policy amendment effective date, each non-employee director is entitled to equity awards totaling 34,100 shares of Common Stock, which total was divided, as determined by the Board in its sole discretion, between stock options and restricted stock units. All such restricted stock units will vest, and all such stock options will vest and become exercisable, in three substantially equal annual installments on March 28, 2025, March 28, 2026, and March 28, 2027, subject to continued service on such applicable vesting date.

Each non-employee director may make an election to receive all or part of his or her annual cash compensation in the form 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.

All fees under the director compensation policy are paid on a quarterly basis and no per meeting fees are paid. The Company reimburses non-employee directors for reasonable expenses incurred in connection with attending Board and committee meetings.

The following table sets forth information regarding the total compensation paid to the Company's non-employee directors in 2024. 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] ($)	Option Awards[2] ($)	Stock Awards[2] ($)	Total ($)	Option Awards Held at December 31, 2024 (#)	Stock Awards Held at December 31, 2024 (#)
June Almenoff, M.D., Ph.D.	$57,517	$205,365	$93,860	$356,742	24,691	9,500
Mitchell Chan	$63,250	$205,365	$93,860	$362,475	24,656	9,500
Jonathan Goldman, M.D.	$41,940	$205,365	$93,860	$341,165	24,600	9,500
Aaron Kantoff	$41,896	$205,365	$93,860	$341,121	24,600	9,500
Gilla Kaplan, Ph.D.	$61,408	$205,365	$93,860	$360,633	24,718	9,500
Magnus Persson, M.D., Ph.D.[3]	$39,205	$—	$—	$39,205	—	—
Samantha Truex	$40,519	$205,365	$93,860	$339,744	24,600	9,500

(1) The amounts reflect cash fees earned for services rendered in fiscal year 2024.

(2) The amounts reflect the aggregate grant date fair value for option and restricted stock unit awards, respectively, granted during 2024 in accordance with ASC 718, excluding the estimate of forfeitures. The assumptions used in valuing these options and restricted stock units are described in Note 12 to our consolidated financial statements for the year ended December 31, 2024. 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.

(3) Dr. Persson served on our Board through August 12, 2024.

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, 2024:

	(A)		(B)		(C)	
Plan category	**Number of Securities to be Issued Upon Exercise of Outstanding Options and Vesting of Restricted 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	2,247,571		$19.59	(1)	1,301,050	(2)
Equity compensation plans not approved by stockholders	384,278	(3)	$21.24		—	
Total	2,631,849		$19.91		1,301,050	

(1) The weighted-average exercise price does not account for the shares issuable upon the vesting of outstanding restricted stock units, which have no exercise price. There were 632,100 unvested restricted stock units outstanding as of December 31, 2024.

(2) Reflects shares of common stock available for future issuance under our Fourth Amended and Restated 2016 Equity Incentive Plan at December 31, 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 year. On January 1, 2025, pursuant to the terms of the 2016 Fourth Amended and Restated Plan, an additional 1,768,393 shares were made available for issuance.

(3) 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).

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 7, 2025 by: (i) each director; (ii) our Named Executive Officer; (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 10,471,934 shares of our common stock outstanding as of March 7, 2025, together with applicable options 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, warrants, and Series C Preferred Stock that are currently exercisable, or exercisable within 60 days after March 7, 2025, are deemed outstanding for the purpose of computing the percentage ownership of the person holding those options, warrants, 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., 540 Gaither Road, Suite 400, Rockville, Maryland 20850.

	Beneficial Ownership [1]	
Beneficial Owner	**Number of Shares [2]**	**Percent of Total**
5% Stockholders:		
BVF Partners, L.P. [3]	1,046,982	9.99%
Ikarian Capital, LLC [4]	1,054,485	9.99%
RA Capital Management, L.P. [5]	1,054,843	9.99%
OrbiMed Advisors, LLC [6]	1,054,843	9.99%
Deep Track Capital, L.P. [7]	1,065,830	9.99%
Boothbay Fund Management, LLC [8]	619,976	5.67%
Affinity Asset Advisors, LLC [9]	550,765	5.26%
Patrick J. Crutcher [10]	549,467	5.25%
Directors and Named Executive Officers:		
Garry Neil, M.D. [11]	137,182	1.29%
June Almenoff, M.D., Ph.D. [12]	8,291	*
Mitchell Chan [13]	8,256	*
Mittie Doyle, M.D., FACR	—	*
Jonthan Goldman, M.D. [14]	8,200	*
Aaron Kantoff [15]	8,200	*
Gilla Kaplan, Ph.D. [16]	8,318	*
Samantha Truex [17]	8,200	*
Jennifer Riley	—	*
Christopher Sullivan [18]	51,166	*
Paul Varki	—	*
All current executive officers and directors as a group	237,813	2.22%
*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 on a Schedule 13G/A filed with the SEC on February 14, 2025 by BVF Partners, L.P. reporting ownership as of December 31, 2024. 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 (i) 550,550 shares beneficially owned by BVF, 1,863 shares underlying certain shares of Series C Preferred Stock, and excluding 2,189,817 shares underlying certain shares of Series C Preferred Stock held by it; (ii) 432,148 shares beneficially owned by BVF2, excluding 1,725,258 shares underlying the shares of Series C Preferred Stock held by it; and (iii) 40,633 shares beneficially owned by Trading Fund OS, excluding 161,614 shares underlying the shares of Series C Preferred Stock held by it. On an aggregated basis, BVF Partners, L.P. owns 4,138.470 shares of Series C Preferred Stock convertible into 4,138,470 shares of common stock, subject to beneficial ownership limitations on an aggregated basis. Mark Lampert, as a director and officer of BVF Inc., may be deemed to beneficially own the 1,046,982 shares beneficially owned by BVF Inc. 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 on a Schedule 13-F filed with the SEC on February 14, 2025 by Ikarian Capital, LLC reporting ownership as of December 31, 2024. Consists of 970,259 shares of common stock and 1,357.806 Series C Preferred Stock convertible into 1,357,806 shares of common stock, subject to beneficial ownership limitations on an aggregated basis. The principal business address of the holder is 100 Crescent Ct., Suite 1620, Dallas, TX 75201.

(5) Based on a Schedule 13-F filed with the SEC on February 14, 2025 by RA Capital Management, L.P. Advisors LLC reporting ownership as of December 31, 2024. Consists of 967,000 shares of common stock and 2,483.100 Series C Preferred Stock convertible into 2,483,100 shares of common stock, subject to beneficial ownership limitations on an aggregated basis. 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 on a Schedule 13-F filed with the SEC on February 14, 2025 by Orbimed Advisors LLC reporting ownership as of December 31, 2024. Consists of 967,000 shares of common stock and 3,173.120 Series C Preferred Stock convertible into 3,173,120 shares of common stock, subject to beneficial ownership limitations on an aggregated basis. The principal business address of the holder is Attn: General Counsel, 601 Lexington Avenue, 54th Floor, New York, NY 10022.

(7) Based on a Schedule 13-F filed with the SEC on February 14, 2025 by Deep Track Capital, LP reporting ownership as of December 31, 2024. Consists of 867,000 shares of common stock and 2,138.090 Series C Preferred Stock convertible into 2,138,090 shares of common stock, subject to beneficial ownership limitations on an aggregated basis. The principal business address of the holder is 200 Greenwich Avenue, 3rd Floor, Greenwich, CT 06830.

(8) Based on a Schedule 13-F filed with the SEC on February 14, 2025 by Boothbay Fund Management, LLC reporting ownership as of December 31, 2024. Consists of 163,992 shares of common stock and 455.984 Series C Preferred Stock convertible into 455,984 shares of common stock, subject to beneficial ownership limitations on an aggregated basis. The principal business address of the holder is 140 East 45th Street, 14th Floor, New York, NY 10017.

(9) Based on a Schedule 13-F filed with the SEC on February 13, 2025 by Affinity Asset Advisors, LLC reporting ownership as of December 31, 2024. Consists of 550,765 shares of common stock. The principal business address of the holder is 767 Third Avenue, New York, NY 10017.

(10) Based on a Schedule 13-G/A filed with the SEC on November 7, 2024 by Patrick J. Crutcher reporting beneficial ownership as of September 30, 2024. Consists of 549,467 shares of common stock, all directly held by Mr. Crutcher and may be deemed beneficially owned by Mr. Crutcher.

(11) Consists of (i) 60 shares of common stock held by Dr. Neil and (ii) 137,182 shares issuable upon the exercise of options currently exercisable or exercisable within 60 days after March 7, 2025.

(12) Consists of 8,291 shares issuable to Dr. Almenoff upon the exercise of options currently exercisable or exercisable with 60 days after March 7, 2025.

(13) Consists of 8,256 shares issuable to Mr. Chan upon the exercise of options currently exercisable or exercisable with 60 days after March 7, 2025.

(14) Consists of 8,200 shares issuable to Dr. Goldman upon the exercise of options currently exercisable or exercisable with 60 days after March 7, 2025.

(15) Consists of 8,200 shares issuable to Mr. Kantoff upon the exercise of options currently exercisable or exercisable with 60 days after March 7, 2025.

(16) Consists of 8,318 shares issuable to Dr. Kaplan upon the exercise of options currently exercisable or exercisable within 60 days after March 7, 2025.

(17) Consists of 8,200 shares issuable to Ms. Truex upon the exercise of options currently exercisable or exercisable with 60 days after March 7, 2025.

(18) Consists of (i) 6 shares of common stock held by Mr. Sullivan and (ii) 51,160 shares issuable upon the exercise of options currently exercisable or exercisable with 60 days after March 7, 2025.

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, 2023 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 and restricted stock units to our 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.

Q1 2023 Equity Financing

On February 7, 2023, the Company closed an underwritten public offering of 15,717 shares of its common stock and warrants to purchase up to 15,717 shares of common stock, at a combined price to the public of $955 per share and warrant, resulting in net proceeds of approximately $13.7 million, after deducting the underwriting discounts and commissions and offering expenses payable by us. The warrants were immediately exercisable at an exercise price of $1,200 per share and are exercisable for one year from the issuance date, or February 2024. Prior to their expiration in February 2024, none of the warrants were exercised. Armistice, who was a significant stockholder of the Company at the time of the financing, participated in the offering by purchasing 1,875 shares of common stock and 1,875 warrants, on the same terms as all other investors. Certain affiliates of Nantahala Capital Management LLC and Point72 Asset Management, L.P., which each beneficially owned greater than 5% of the Company's outstanding common stock at the time of the offering, participated in the offering on the same terms as all other investors.

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: Dr. Almenoff, Mr. Chan, Dr. Goldman, Mr. Kantoff, Dr. Kaplan, 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, 2024 and 2023, 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,	
	2024	**2023**
Audit fees[(1)]	$ 942,489	$ 622,500
Audit-related fees[(2)]	18,000	18,000
Tax fees[(3)]	—	—
All other fees[(4)]	1,995	1,995
Total	$ 962,484	$ 642,495

[(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 increase in 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:

Report of Independent Registered Public Accounting Firm (PCAOB ID: 42)	F-2
Consolidated Balance Sheets as of December 31, 2024 and 2023	F-4
Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2024 and 2023	F-5
Consolidated Statements of Mezzanine and Stockholders' Equity for the years ended December 31, 2024 and 2023	F-6
Consolidated Statements of Cash Flows for the years ended December 31, 2024 and 2023	F-8
Notes to Consolidated Financial Statements	F-11

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
2.4*#	Purchase Agreement, dated September 11, 2023, by and between AUG Therapeutics, LLC and Avalo Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed on September 12, 2023).
2.5	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 3.1 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 3.1 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	Second Amended and Restated Investors' Rights Agreement, dated as of July 11, 2014 (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-1 filed on June 12, 2015).
4.2	Specimen Unit Certificate (incorporated by reference to Exhibit 4.13 to the Registration Statement on Form S-1/A filed on October 13, 2015).
4.3	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.3 to the Registration Statement on Form S-8 filed on May 20, 2016).
4.4.1	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).
4.4.2	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).
4.4.3	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).
4.4.4	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).
4.4.5	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).

4.4.6	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).
4.4.7	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).
4.4.8	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).
4.5 ‡	Description of Registered Securities.
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	Guarantee, dated as of November 1, 2019, made by Cerecor Inc. in favor of Deerfield CSF, LLC (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on November 4, 2019).
10.2.2	Contribution Agreement, made and entered into as of November 1, 2019, by and among Cerecor Inc., Armistice Capital Master Fund, Ltd. and Avadel US Holdings Inc. (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on November 4, 2019).
10.3.1 **	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).

10.3.2 **	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).
10.4.1 *	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).
10.4.2 **	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).
10.4.3 **	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).
10.5.1	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).
10.5.2	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).
10.5.3	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).
10.6 **	Exclusive Patent License Agreement, dated June 22, 2021, by and between Sanford Burnham Prebys Medical Discovery Institute and Cerecor Inc. (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed on August 2, 2021).
10.7.1 *	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).
10.7.2 *	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).
10.8.1	Sales Agreement, dated as of May 4, 2023, between Avalo Therapeutics, Inc. and Oppenheimer & Co. Inc. (incorporated by reference to Exhibit 1.1 to the Current Report on Form 8-K filed on May 4, 2023).
10.8.2	Amendment No. 1 to the Sales Agreement, dated as of August 7, 2023, between Avalo Therapeutics, Inc. and Oppenheimer & Co. Inc. (incorporated by reference to Exhibit 1.1 to the Current Report on Form 8-K filed on August 7, 2023).

10.9.1	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).
10.9.2 *	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed on March 28, 2024.)
10.10	Lease dated September 14, 2018, by and between FP 540 Gaither, LLC and Cerecor Inc. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on September 18, 2018).
10.11 +	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).
10.12 +	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).
10.13	Non-Employee Director Compensation Policy, amended June 6, 2024, with an effective date of July 1, 2024 (incorporated by reference to Exhibit 10.4 to the Quarterly Report on Form 10-Q filed on November 7, 2024).
10.14 ‡	Form of Director Indemnification Agreement.
10.15.1 +	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).
10.15.2 +	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).
10.16.1 +	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).
10.16.2 +	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).
10.16.3 +	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).
10.17.1 +	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).
10.17.2 +	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).

10.18 +	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).
10.19 +	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).
19.1 ‡	Insider Trading Policy, dated May 15, 2018.
21.1 ‡	List of Subsidiaries of the Registrant.
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.
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).

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* 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 20, 2025

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.**	President and Chief Executive Officer, Chairman of the Board of Directors and Director *(Principal Executive Officer)*	March 20, 2025
/s/ Christopher Sullivan **Christopher Sullivan**	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 20, 2025
/s/ June Almenoff, M.D., Ph.D. **June Almenoff, M.D., Ph.D.**	Director	March 20, 2025
/s/ Mitchell Chan **Mitchell Chan**	Director	March 20, 2025
/s/ Jonathan Goldman, M.D. **Jonathan Goldman, M.D.**	Director	March 20, 2025
/s/ Aaron Kantoff **Aaron Kantoff**	Director	March 20, 2025
/s/ Gilla Kaplan, Ph.D. **Gilla Kaplan, Ph.D.**	Director	March 20, 2025
/s/ Samantha Truex **Samantha Truex**	Director	March 20, 2025

AVALO THERAPEUTICS, INC.
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Report of Independent Registered Public Accounting Firm

To the Shareholders 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, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, mezzanine equity and stockholders' equity and cash flows for the years then ended, 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, 2024 and 2023, and the results of its operations and its cash flows for the years then ended, 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, 2024, the Company recorded an $8.5 million derivative liability related to future milestone payments and 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 of the 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.

Accounting for the Private Placement Financing

Description of the Matter

As more fully described in Note 11 of the consolidated financial statements, during March 2024, the Company closed a private placement investment with institutional investors in which the investors received (i) 19,946 shares of Series C Preferred Stock and (ii) warrants to purchase up to an aggregate of 11,967,526 shares of Avalo's common stock, resulting in the Company receiving an initial upfront gross investment of $115.6 million.

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 warrant 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, which also resulted in no amounts allocated to the Series C Preferred Stock. To determine the fair value of the warrant liability the Company applied a Black Scholes model, which required assumptions including the value of the stock on the measurement date, exercise price, expected term, expected volatility, and the risk-free interest rate.

Auditing the Company's accounting for the private placement financing was complex due to the judgment required in evaluating whether each instrument should be classified as a liability or in shareholders' equity and the appropriateness of the assumptions used in the Black Scholes model.

How We Addressed the Matter in Our Audit

To test the accounting for the private placement financing, our procedures included, among others, obtaining and reviewing the executed agreement and the Company's related technical accounting analysis. We involved professionals with specialized skills and knowledge to assist in evaluating the agreement to determine the appropriateness of the Company's application of the relevant accounting guidance for the preferred stock and warrants. We tested the fair value of the warrant liability by 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.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2013.
Tysons, Virginia
March 20, 2025

AVALO THERAPEUTICS, INC. and SUBSIDIARIES

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

	December 31,	
	2024	2023
Assets		
Current assets:		
Cash and cash equivalents	$ 134,546	$ 7,415
Other receivables	611	136
Prepaid expenses and other current assets	3,714	843
Restricted cash, current portion	19	1
Total current assets	138,890	8,395
Property and equipment, net	1,209	1,965
Goodwill	10,502	10,502
Restricted cash, net of current portion	131	131
Total assets	$ 150,732	$ 20,993
Liabilities, mezzanine equity and stockholders' equity		
Current liabilities:		
Accounts payable	$ 283	$ 446
Accrued expenses and other current liabilities	6,317	4,172
Derivative liability, current	360	—
Total current liabilities	6,960	4,618
Royalty obligation	2,000	2,000
Deferred tax liability, net	270	155
Derivative liability, non-current	8,120	5,550
Other long-term liabilities	350	1,366
Total liabilities	17,700	13,689
Mezzanine equity:		
Series D Preferred Stock—$0.001 par value; 1 and 0 shares of Series D Preferred Stock authorized at December 31, 2024 and 2023, respectively; 1 and 0 shares of Series D Preferred Stock issued and outstanding at December 31, 2024 and 2023, respectively	—	—
Series E Preferred Stock—$0.001 par value; 1 and 0 shares of Series E Preferred Stock authorized at December 31, 2024 and 2023, respectively; 1 and 0 shares of Series E Preferred Stock issued and outstanding at December 31, 2024 and 2023, respectively	—	—
Stockholders' equity:		
Common stock—$0.001 par value; 200,000,000 shares authorized at December 31, 2024 and 2023; 10,471,934 and 801,746 shares issued and outstanding at December 31, 2024 and 2023, respectively	10	1
Series C Preferred Stock—$0.001 par value; 34,326 and 0 shares of Series C Preferred Stock authorized at December 31, 2024 and 2023, respectively, 24,896 and 0 shares of Series C Preferred Stock issued and outstanding at December 31, 2024 and 2023, respectively	—	—
Additional paid-in capital	503,285	342,437
Accumulated deficit	(370,263)	(335,134)
Total stockholders' equity	133,032	7,304
Total liabilities, mezzanine equity and stockholders' equity	$ 150,732	$ 20,993

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,	
	2024	2023
Revenues:		
Product revenue, net	$ 441	$ 1,408
License and other revenue	—	516
Total revenues, net	441	1,924
Operating expenses:		
Cost of product sales	(366)	1,284
Research and development	24,437	13,784
Acquired in-process research and development	27,641	—
General and administrative	17,241	10,300
Goodwill impairment	—	3,907
Total operating expenses	68,953	29,275
Loss from operations	(68,512)	(27,351)
Other income (expense):		
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)	—
Change in fair value of derivative liability	(2,930)	(720)
Interest income (expense), net	3,317	(3,417)
Other expense, net	(5)	(42)
Total other income (expense), net	33,497	(4,179)
Loss before income taxes	(35,015)	(31,530)
Income tax expense	114	14
Net loss	$ (35,129)	$ (31,544)
Net loss per share of common stock:		
Basic	$ (7.94)	$ (113.58)
Diluted	$ (20.91)	$ (113.58)

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 capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, December 31, 2022	—	$ —	39,294	$ —	—	$ —	$ 292,909	$ (303,824)	$ (10,915)
Issuance of common stock and warrants in underwritten public offering, net	—	—	15,709	—	—	—	13,749	—	13,749
Issuance of common shares pursuant to ATM Program, net	—	—	746,076	1	—	—	32,469	—	32,470
Retirement of common shares in exchange for pre-funded warrants	—	—	(5,417)	—	—	—	(3,874)	234	(3,640)
Issuance of pre-funded warrants in exchange or retirement of common shares	—	—	—	—	—	—	3,640	—	3,640
Exercise of pre-funded warrants for common shares	—	—	5,850	—	—	—	—	—	—
Shares purchased through employee stock purchase plan	—	—	99	—	—	—	67	—	67
Impact of reverse stock split fractional share round-up	—	—	135	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	3,477	—	3,477
Net loss	—	—	—	—	—	—	—	(31,544)	(31,544)
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

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,	
	2024	**2023**
Operating activities		
Net loss	$ (35,129)	$ (31,544)
Adjustments to reconcile net loss used in operating activities:		
Depreciation and amortization	169	158
Stock-based compensation	5,852	3,477
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)	—
Change in fair value of derivative liability	2,930	720
Lease early termination fee	(309)	—
Accretion of debt discount	—	1,828
Goodwill impairment	—	3,907
Deferred taxes	114	14
Changes in assets and liabilities:		
Other receivables	(475)	1,783
Inventory, net	—	20
Prepaid expenses and other assets	(2,871)	447
Lease incentive	—	158
Accounts payable	(163)	(2,436)
Deferred revenue	—	(88)
Accrued expenses and other liabilities, excluding lease liability	(1,111)	(9,048)
Lease liability, net	(88)	(76)
Net cash used in operating activities	(49,056)	(30,680)
Investing activities		
Cash assumed from AlmataBio Transaction	356	—
Leasehold improvements	—	(158)
Disposal of property and equipment	—	25
Net cash provided by (used in) investing activities	356	(133)
Financing activities		
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)	
Proceeds from sale of common stock pursuant to ATM Program, net	—	32,470
Proceeds from issuance of common stock in underwritten public offering, net	—	13,749
Principal payments on Notes	—	(21,244)
Proceeds from issuance of common stock under employee stock purchase plan	68	67
Net cash provided by financing activities	175,849	25,042
Increase (decrease) in cash, cash equivalents, and restricted cash	127,149	(5,771)
Cash, cash equivalents, and restricted cash at beginning of period	7,547	13,318
Cash, cash equivalents, and restricted cash at end of period	$ 134,696	$ 7,547

Supplemental disclosures of cash flow information		
Cash paid for interest	$ —	$ 1,925
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)	$ —
Fair value of common stock retired in exchange for issuance of pre-funded warrants	$ —	$ 3,640

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,	
	2024	**2023**
Cash and cash equivalents	$ 134,546	$ 7,415
Restricted cash, current	19	1
Restricted cash, non-current	131	131
Total cash, cash equivalents and restricted cash	$ 134,696	$ 7,547

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 focused on the treatment of immune dysregulation. Avalo's lead asset is AVTX-009, an anti-IL-1β monoclonal antibody ("mAb") targeting inflammatory diseases.

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 and cash losses from 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, 2024, Avalo generated a net loss of $35.1 million and negative cash flows from operations of $49.1 million. As of December 31, 2024, Avalo had $134.5 million in cash and cash equivalents. For the year ended December 31, 2024, the Company raised approximately $175.8 million of net proceeds from a private placement and the subsequent exercise of warrants issued in the private placement.

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 and cash equivalents 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.

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 three months or less when purchased to be cash equivalents. The carrying amounts reported in the balance sheets for cash and cash equivalents are valued at cost, which approximates their fair value.

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 revalued 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. The assessment of whether the warrants are accounted for as equity-classified or liability-classified instruments is re-evaluated on a periodic basis.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash and cash equivalents. The Company maintains a portion of its cash and cash equivalent balances in the form of a money market account with a financial institution that management believes to be creditworthy. The Company has no financial instruments with off-balance sheet risk of loss.

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 two operating leases, which both serve 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. The Company uses the lesser of the lease term or ten years for leasehold improvements. 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 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, 2024, 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.

Notes Payable

Notes payable were recorded on the balance sheet at carrying value, which was the gross balance (inclusive of the final payment fee for the Note (as defined in Note 10)), less the unamortized debt discount and issuance costs. All fees, costs paid to the Lenders (as defined in Note 10) and all direct costs incurred by the Company were recognized as a debt discount and were amortized to interest expense using the effective interest method over the life of the loan. In 2023, the Company repaid all outstanding principal and interest under the Loan Agreement (as defined in Note 10) and all obligations of the parties under the Loan Agreement were deemed satisfied and terminated. As such, there was no remaining notes payable balance at December 31, 2024 and 2023.

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 are 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, one customer has 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 will be 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 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 life 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 as opposed to being estimated at the time of grant and revised.

For restricted stock units ("RSUs") issued to employees and members of the board of directors for their services, the Company measures the RSUs using the stock price on the date of grant. The compensation for RSUs is recognized on a straight-line basis over the vesting period.

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*. 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, 2024, the Company did not believe any material uncertain tax positions were present.

Comprehensive Loss

Comprehensive loss comprises net loss and other changes in equity that are excluded from net loss. For the years ended December 31, 2024 and 2023, the Company's net loss was equal to comprehensive loss and, accordingly, no additional disclosure is presented.

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which requires enhanced disclosure of significant segment expenses on an annual and interim basis.
The new standard was adopted effective December 15, 2024. The adoption of this ASU has not had a material impact on our financial statements. Refer to Note 15 for additional information.

Recently Issued Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU 2023-09, Income taxes (Topic 740): Improvements to Income Tax Disclosures, which amends guidance to enhance the transparency and decision usefulness of income tax disclosures. It is effective for fiscal years beginning after December 15, 2024. The Company is currently evaluating the impact.

In November 2024, the FASB issued ASU 2024-03, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, which requires a public entity to disclose additional information about specific expense categories in the notes to the financial statements on an annual and interim basis. It is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. In January 2025, the FASB issued ASU 2025-01 to clarify that all public entities, including non-calendar year-end entities, should adopt the disclosure requirements of ASU 2024-03. The Company is currently evaluating the impact.

3. Asset Acquisition

AlmataBio Transaction

On March 27, 2024, the Company acquired 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 AVTX-009, and $15.0 million due upon the first patient dosed in a Phase 3 trial for 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 is 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 IPR&D, specifically 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 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. 2,063 *of the 2,412 shares of Series C Preferred Stock were converted into* 2,062,930 *shares of common stock on August 13, 2024 upon Company stockholder approval and subject to beneficial ownership limitations.*

[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 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

Product Revenue, net

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 of prescription drugs for the year ended December 31, 2024. The Company recognized $0.4 million of net product revenue for the year ended December 31, 2024 related to adjustments in gross-to-net estimates, as noted above. For the year ended December 31, 2023, the Company's only two customers accounted for approximately 58% and 42% of the Company's total net product revenues of $1.4 million.

Aytu BioScience, Inc. ("Aytu"), to which the Company sold its rights, title, and interests in assets relating to certain commercialized products in 2019 (the "Aytu Transaction"), managed Millipred® commercial operations until August 31, 2021 pursuant to transition services agreements, which included managing the third-party logistics provider. As a result, Aytu collected cash on behalf of Avalo for revenue generated by sales of Millipred® from the second quarter of 2020 through the third quarter of 2021.

The transition services agreement allowed Aytu to withhold up to $1.0 million until December 2024, and as of December 31, 2024 the total receivable due to Avalo was $0.5 million, which was recognized within other receivables on the consolidated balance sheet. The Company collected the receivable in January 2025.

License and Other Revenue

There was no license and other revenue for the year ended December 31, 2024. In the fourth quarter of 2023, the Company closed the transaction under the asset purchase agreement (the "Purchase Agreement") to sell its rights, title and interest in, assets relating to AVTX-801, AVTX-802 and AVTX-803 (collectively, the "800 Series") to AUG Therapeutics, LLC ("AUG"). Pursuant to the Purchase Agreement, 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 recognized $0.5 million as license and other revenue for the year ended December 31, 2023. Avalo is also entitled to a contingent milestone payments as disclosed in Note 14.

5. Net Loss Per Share

The Company had two classes of stock outstanding during the year ended December 31, 2024, common stock and preferred stock, and had only common stock outstanding during the year ended December 31, 2023. 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, 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. The weighted average number of common shares outstanding as of December 31, 2023, includes the weighted average effect of pre-funded warrants, the exercise of which required nominal considerations for the delivery of the shares of common stock. There were no pre-funded warrants outstanding as of December 31, 2024 and 2023.

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, 2024 and 2023 (in thousands, except per share amounts):

	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)

	Year Ended December 31, 2023	
	Common stock	
Net loss	$	(31,544)
Weighted average shares		277,727
Basic and diluted net loss per share	$	(113.58)

The following outstanding securities have been excluded from the computation of diluted weighted shares outstanding for the years ended December 31, 2024 and 2023, as they could have been anti-dilutive:

	December 31,	
	2024[3]	2023
Stock options	1,999,749	7,559
Warrants on common stock[1]	148	17,254
Series C Preferred Stock (as-convertible to common stock)[2]	24,895,920	—
Restricted Stock Units	632,100	—

[1] *The weighted average number of common shares outstanding for the year ended December 31, 2023 includes the weighted average effect of 2,003 pre-funded warrants, because their exercise price was nominal. There were no pre-funded warrants outstanding as of December 31, 2024 and 2023.*

[2] *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.*

[3] *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, 2024 pursuant to the guidance on contingently issuable shares.*

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 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, 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)
Assets			
Investments in money market funds*	$ 133,148	$ —	$ —
Liabilities			
Derivative liability	$ —	$ —	$ 8,480

	December 31, 2023		
	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)
Assets			
Investments in money market funds*	$ 7,077	$ —	$ —
Liabilities			
Derivative liability	$ —	$ —	$ 5,550

**Investments in money market funds are reflected in cash and cash equivalents on the accompanying consolidated balance sheets.*

As of December 31, 2024 and 2023, the Company's financial instruments included cash and cash equivalents, restricted cash, other receivables, prepaid and other current assets, accounts payable, accrued expenses and other current liabilities, and derivative liability.

The carrying amounts reported in the accompanying financial statements for cash and cash equivalents, restricted cash, accounts receivable, other receivables, 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 1 Valuation

There was no goodwill impairment recognized for the year ended December 31, 2024. A goodwill impairment loss of $3.9 million was recognized for the year ended December 31, 2023. The fair value of the reporting unit was estimated using the market approach. The Company utilized the closing stock price on the last day of the fiscal year, which is considered a Level 1 input pursuant to ASC 820, to calculate the reporting unit's fair value. The $3.9 million impairment loss recognized represents the difference between the reporting unit's carrying value and its fair value. See Note 8 for additional information.

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, 2024 and 2023:

	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	Total
Balance at December 31, 2022	$ 4,830	$ 4,830
Change in fair value	720	720
Balance at December 31, 2023	$ 5,550	$ 5,550

Warrant Liability

On March 28, 2024, the Company closed a private placement in which the investors received (i) 19,946 shares of 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 is then exercisable into) with an exercise price of $5.796933. 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, 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 including the value of the stock on the measurement date, exercise price, expected term, expected volatility, and the risk-free interest rate. Certain assumptions, including the expected term and expected volatility, were subjective and required judgment. 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. Upon exercise of the warrants in the fourth quarter of 2024, the final fair value of the warrant liability was $73.3 million. Given the full exercise of the warrants, there was no warrant liability as of December 31, 2024, resulting in the $121.6 million gain on the change in fair value recognized in other income (expense), net in the accompanying consolidated financial statements of operations and comprehensive loss for the year ended December 31, 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.

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 Master Fund Ltd. (an affiliate of Armistice Capital, LLC, and collectively "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 Pharmaceuticals, 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, including up to $6.25 million of development milestones, up to $67.5 million in sales-based milestones, and royalty payments 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 include 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, all of which 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 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 AVX-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, 2024, the fair value of the derivative liability was $8.5 million, all of which was attributable to the AVTX-007 Milestones and Royalties and $0.4 million of which was classified as a current liability with the remainder classified as a non-current liability as of December 31, 2024. For the year ended December 31, 2024, the $2.9 million loss on the change in fair value was recognized in other income (expense), net in the accompanying consolidated statements of operations and comprehensive loss.

The fair value of the AVTX-501 Milestone was deemed to be $0.0 million, driven by less than 1% probability of success based on Avalo's interpretation of a recent announcement from J&J noting the discontinuation of the aticaprant depression program (previously referred to as AVTX-501 by Avalo), which was the only indication that we are aware they were pursuing, 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 $1.8 billion in atopic dermatitis, which is a much larger market opportunity than adult-onset Still's disease (the previous indication being pursued that was contemplated in valuations through the first quarter of 2024), an approximate 17% probability of success, and an estimated time to commercialization of approximately 6.0 years. 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 the fair value.

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.

No other changes in valuation techniques or inputs occurred during the years ended December 31, 2024 and 2023. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the years ended December 31, 2024 and 2023.

7. Property and Equipment

Property and equipment as of December 31, 2024 and 2023 consisted of the following (in thousands):

	December 31,	
	2024	2023
Furniture and equipment	$ 248	$ 248
Computers and software	34	34
Right-of-use assets	741	1,329
Leasehold improvements	896	896
Total property and equipment	1,919	2,507
Less accumulated depreciation	(710)	(542)
Property and equipment, net	$ 1,209	$ 1,965

Depreciation expense was $0.2 million for each of the years ended December 31, 2024 and 2023.

Leases

Avalo currently occupies two leased properties, both of which serve as administrative office space. The Company determined that both leases are operating leases based on the lease classification test performed at lease commencement.

The initial annual base rent for the Company's office located in Chesterbrook, Pennsylvania 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.

The annual base rent for the Company's office located in Rockville, Maryland is $0.2 million, 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. In the fourth quarter of 2024, the Company elected to early-terminate the lease effective January 31, 2026, which represents the sixth anniversary of the first annual fixed rent payment and paid the $0.3 million contractual early termination fee in December 2024. As a result of the early-termination, the lease liability and ROU asset were remeasured and reduced by $0.3 million.

The weighted average remaining term of the operating leases at December 31, 2024 was 1.9 years.

Supplemental balance sheet information related to the leased properties include (in thousands):

	As of December 31,	
	2024	2023
Property and equipment, net	$ 741	$ 1,329
Accrued expenses and other current liabilities	$ 568	$ 537
Other long-term liabilities	350	1,366
Total operating lease liabilities	$ 918	$ 1,903

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 9.5% to determine the present value of the lease payments.

The components of lease expense for the years ended December 31, 2024 and 2023 were as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Operating lease cost*	$ 456	$ 460

**Includes short-term leases, which are immaterial.*

The following table shows a maturity analysis of the operating lease liability as of December 31, 2024 (in thousands):

	Undiscounted Cash Flows
2025	558
2026	392
2027	63
Thereafter	—
Total lease payments	$ 1,013
Less implied interest	(95)
Total	$ 918

8. Goodwill

There were no changes in the carrying amount of goodwill for the year ended December 31, 2024.

The changes in the carrying amount of goodwill for the year ended December 31, 2023 was as follows (in thousands):

	Goodwill
Balance as of December 31, 2022	$ 14,409
Goodwill impairment	(3,907)
Balance as of December 31, 2023	$ 10,502

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.

The Company recognized $3.9 million of goodwill impairment loss for the year ended December 31, 2023 as part of its annual goodwill impairment test performed on the last day of the fiscal year. The impairment loss recognized represented the difference between the reporting unit's carrying value and its fair value as of December 31, 2023. Because the Company consists of one reporting unit, the Company's carrying value and fair value represent the reporting unit's carrying value and fair value, respectively. The fair value of the reporting unit was estimated using the market approach. The Company utilized its closing stock price on the last day of the fiscal year, which is considered a Level 1 input pursuant to ASC 820, to calculate the reporting unit's fair value.

9. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities as of December 31, 2024 and 2023 consisted of the following (in thousands):

	December 31,	
	2024	2023
Research and development	$ 1,625	$ 352
Compensation and benefits	2,883	580
General and administrative	380	830
Commercial operations	534	1,873
Royalty payment	327	—
Lease liability, current	568	537
Total accrued expenses and other current liabilities	$ 6,317	$ 4,172

10. Notes Payable

On June 4, 2021, the Company entered into a $35.0 million venture loan and security agreement (the "Loan Agreement") with Horizon Technology Finance Corporation ("Horizon") and Powerscourt Investments, XXV, LP ("Powerscourt", and together with Horizon, the "Lenders"). Between June and September 2021, the Company borrowed the full $35.0 million (the "Note") available under the Loan Agreement. In the second quarter of 2022, the Company, as collectively agreed upon with the Lenders, prepaid $15.0 million of principal and accrued interest. In June of 2023, the Company, as collectively agreed upon with the Lenders, prepaid $6.0 million of principal. On September 22, 2023, the Company and the Lenders entered into a Payoff Letter (the "Payoff Letter"), pursuant to which the Company repaid all outstanding principal, inclusive of the final payment fee, and interest under the Loan Agreement in the aggregate amount of $14.3 million. As a result of the payment, all obligations of the parties under the Loan Agreement were deemed satisfied and terminated.

On June 4, 2021, pursuant to the Loan Agreement, the Company issued warrants to the Lenders to purchase 148 shares of the Company's common stock with an exercise price of $7,488 per share (the "Loan Warrants"). The Loan Warrants are exercisable for ten years from the date of issuance. Pursuant to the Payoff Letter, Avalo's obligations under the Loan Warrants shall survive pursuant to the original terms at issuance. The Loan Warrants, which met equity classification, were recognized as a component of permanent stockholders' equity within additional paid-in-capital and were recorded at the issuance date using a relative fair value method. The Company recognized debt issuance costs and the amount allocated to the Loan Warrants as a debt discount on the date of issuance and amortized these costs into interest expense using the effective interest method over the original term of the loan. As a result of the payoff in the third quarter of 2023, the Company accelerated the remaining $0.9 million amortization of the debt discount, which was recognized as interest expense for the year ended December 31, 2023.

No Loan Warrants have been exercised as of December 31, 2024.

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, 2024, 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, in conjunction with the acquisition of AlmataBio, the Company issued former AlmataBio stockholders (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 is 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. Both the private placement and warrant exercise transaction costs were expensed within other income (expense), 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. Each share of Series C Preferred Stock is convertible into 1,000 shares of common stock, subject to beneficial ownership limitations.

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 is 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 *"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, 2024, 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, 2024, there were 24,896 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 are 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. As of December 31, 2024, the remaining 349 shares of Series C Preferred Stock held by the former AlmataBio stockholders, with a carrying value of $1.7 million, was reclassified into permanent equity on the consolidated balance sheet. Additionally, the 11,186.267 shares of Series C Preferred Stock issued as a result of the warrant exercises in the fourth quarter of 2024 with a carrying value of $133.0 million, were recognized as a component of permanent stockholders' equity within additional paid in capital on the Company's 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.

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 share of 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. Although the Series D and Series E Preferred Stock do not provide the holders with substantive economics, the Series D and Series E Preferred Stock were issued solely to allow for the institutional investors to appoint a director to the Company's board of directors. Given 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

On May 4, 2023, the Company entered into an "at-the-market" sales agreement (the "Sales Agreement") with Oppenheimer & Co. Inc. ("Oppenheimer"), pursuant to which the Company may sell from time to time, shares of its common stock having an aggregate offering price of up to $9,032,567 through Oppenheimer. In August 2023, the Company and Oppenheimer entered into an amendment to the Sales Agreement (the "Amended Sales Agreement") to increase the aggregate offering amount under the Sales Agreement to $50,000,000 inclusive of shares sold prior to the amendment. During the year ended December 31, 2023, the Company sold approximately 0.7 million shares under the ATM program for net proceeds of approximately $32.5 million. There were no sales under the ATM program during the year ended December 31, 2024.

Exchange Agreement

In May of 2023, the Company entered into an exchange agreement (the "Exchange Agreement") with entities affiliated with Venrock Healthcare Capital Partners ("Venrock"), pursuant to which the Company exchanged an aggregate of 5,417 shares of the Company's common stock, par value $0.001 per share, owned by Venrock, for pre-funded warrants (the "Exchanged Warrants") to purchase an aggregate of 5,417 shares of common stock (subject to adjustment in the event of stock splits, recapitalization and other similar events affecting common stock), with an exercise price of $0.24 per share.

The Exchange Warrants were exercisable at any time, except that the Exchange Warrants would not be exercisable by Venrock if, upon giving effect immediately prior thereto, Venrock would beneficially own more than 9.99% of the total number of issued and outstanding Avalo common stock, which percentage could change at the holders' election to any amount less than or equal to 19.99% upon 61 days' notice to the Company. Venrock exercised the Exchanged Warrants in full in September 2023.

In accordance with ASC 505, *Equity*, in the second quarter of 2023, the Company recorded the retirement of the common stock exchanged as a reduction of common shares outstanding and a corresponding impact to additional paid-in-capital and accumulated deficit at the fair value of the Exchange Warrants on the issuance date. The Exchange Warrants were classified as equity in accordance with ASC 480, *Distinguishing Liabilities from Equity*, and the fair value of the Exchange Warrants was recorded as a credit to additional paid-in-capital and is not subject to remeasurement. The Company determined that the fair value of the Exchange Warrants is substantially similar to the fair value of the retired shares on the issuance date due to the negligible exercise price for the Exchange Warrants.

Q1 2023 Financing

On February 7, 2023, the Company closed an underwritten public offering of 15,717 shares of its common stock and warrants to purchase up to 15,717 shares of common stock, at a combined price to the public of $955 per share and warrant, resulting in net proceeds of approximately $13.7 million, after deducting the underwriting discounts and commissions and offering expenses payable by us. The warrants were immediately exercisable at an exercise price of $1,200 per share and were exercisable for one year from the issuance date, or February 2024. Prior to their expiration in February 2024, none of the warrants were exercised. Armistice, who was a significant stockholder of the Company at the time of the financing, participated in the offering by purchasing 1,875 shares of common stock and 1,875 warrants, on the same terms as all other investors.

Certain affiliates of Nantahala Capital Management LLC and Point72 Asset Management, L.P., which each beneficially owned greater than 5% of the Company's outstanding common stock at the time of the offering, participated in the offering on the same terms as all other investors.

The warrants were classified as a component of permanent stockholders' equity within additional paid-in capital. The warrants were equity classified because they (i) were freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, (ii) were immediately exercisable, (iii) did not embody an obligation for the Company to repurchase its shares, (iv) permitted the holders to receive a fixed number of shares of common stock upon exercise, (v) were indexed to the Company's common stock and (vi) met the equity classification criteria. In addition, such warrants did not provide any guarantee of value or return.

Common Stock Warrants

At December 31, 2024, 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

2016 Equity Incentive 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. 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. Upon approval of the 2016 Fourth Amended Plan on August 13, 2024, the number of shares available for issuance increased by 3,508,804 shares. As of December 31, 2024, there were 1,301,050 shares available for future issuance under the 2016 Fourth Amended Plan. On January 1, 2025, pursuant to the terms of the 2016 Fourth Amended Plan, an additional 1,768,393 shares were made available for issuance.

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 directors typically vest immediately or over a period of one or three years. 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 includes expense related to stock options, restricted stock units and employee stock purchase plan shares. The amount of stock-based compensation expense recognized for the years ended December 31, 2024 and 2023 was as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Research and development	$ 2,402	$ 1,318
General and administrative	3,450	2,157
Total stock-based compensation	$ 5,852	$ 3,475

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, 2024 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)
Balance at December 31, 2023	7,211	$ 3,191.97	$ 1,930.00	8.3
Granted	1,993,100	$ 10.47	$ 9.04	
Forfeited	(27)	$ 323.13	$ 232.02	
Expired	(535)	$ 7,588.53	$ 3,731.46	
Balance at December 31, 2024	1,999,749	$ 19.91	$ 14.98	9.6
Exercisable at December 31, 2024	5,499	$ 3,202.54	$ 1,995.94	7.3

On August 13, 2024, as part of its annual stock option award, the Company granted (i) options with service-based vesting conditions to purchase 1.4 million shares of common stock to its employees that vest over four years and (ii) options with service-based vesting conditions to purchase 0.1 million shares of common stock to its non-employee directors that vest over three years. Additionally, in June and July 2024, the Company granted 0.2 million options to each of its newly appointed Chief Legal Officer and newly appointed Chief Medical Officer. The options were granted as inducement option grants pursuant to Nasdaq Listing Rule 5635(c)(4) and are subject to service-based vesting conditions.

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. As of December 31, 2024, the aggregate intrinsic value of options outstanding and the aggregate intrinsic value of options currently exercisable was zero. There were 2,518 options that vested during the year ended December 31, 2024, with a weighted average exercise price of $1,217.35 per share. The total grant date fair value of shares which vested during the years ended December 31, 2024 and 2023 was $2.2 million and $3.4 million, respectively.

The Company recognized stock-based compensation expense of $4.5 million and $3.3 million related to stock options with service-based vesting conditions for the years ended December 31, 2024 and 2023, respectively. At December 31, 2024, there was $16.4 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 3.1 years.

On January 1, 2025, the Company granted its newly appointed Chief Strategy Officer options with service-based vesting conditions to purchase 150,000 shares of common stock with an exercise price of $7.43 as an inducement option grant pursuant to Nasdaq Listing Rule 5635(c)(4). Additionally, on January 28, 2025, as part of its annual stock option award, the Company granted options with service-based vesting conditions to purchase 1.5 million shares of common stock to its employees that vest over four years.

Stock-based compensation assumptions

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, 2024 and 2023:

	Year Ended December 31,					
Service-based options	**2024**			**2023**		
Expected term of options (in years)	5.81	—	6.25	5.00	—	6.25
Expected stock price volatility	113.1%	—	116.9%	89.8%	—	146.0%
Risk-free interest rate	3.70%	—	4.26%	3.43%	—	4.13%
Expected annual dividend yield	0%			0%		

The valuation assumptions were determined as follows:

- **Expected term of options:** Due to lack of sufficient historical data, the Company estimates the expected life of its stock options with service-based vesting granted to employees and members of the board of directors as the 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. There was no RSU activity for the year ended December 31, 2023. A summary of RSU activity for the year ended December 31, 2024 is as follows:

	RSUs Outstanding	
	Number of shares	Weighted average grant date fair value
Balance at Unvested RSUs at December 31, 2023	—	$ —
Granted	632,100	9.88
Unvested RSUs at December 31, 2024	632,100	$ 9.88

The RSUs, which were granted on August 13, 2024, vest annually over a three-year period beginning on March 28, 2025. The Company recognized stock-based compensation expense of $1.3 million related to RSUs for the year ended December 31, 2024. At December 31, 2024, there was $5.0 million of total unrecognized compensation cost related to RSUs. The unrecognized compensation cost is expected to be recognized over a weighted-average period of 2.2 years.

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, 2024, 226,577 shares remained available for issuance. On January 1, 2025, the number of shares available for issuance under the ESPP increased by 353,679.

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 $0.1 million for the year ended December 31, 2024 and $0.2 million for the year ended December 31, 2023.

13. Income Taxes

The Company accounts for income taxes in accordance with ASC 740, *Income Taxes* ("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, 2024. Tax years beginning in 2021 are generally subject to examination by taxing authorities, although net operating losses 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, 2024 and 2023. 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, 2024 and 2023 (in thousands):

	December 31,	
	2024	**2023**
Current:		
Federal	$ —	$ —
State	—	—
Total Current	—	—
Deferred:		
Federal	24	24
State	90	(10)
Total Deferred	114	14
Net income tax expense	$ 114	$ 14

The net deferred tax assets (liabilities) consisted of the following for the years ended December 31, 2024 and 2023 (in thousands):

	December 31,	
	2024	2023
Deferred tax assets (liabilities):		
Net operating losses	$ 42,689	$ 37,268
Tax credits	6,263	5,854
Capitalized research and development	10,803	6,945
Stock-based compensation	1,651	3,557
Basis difference in tangible and intangible assets, net	1,811	1,843
Accrued compensation	691	118
Installment sale and revenue recognition	2,535	1,601
Other reserves	148	336
Lease liability	225	410
Prepaid expenses	(227)	(118)
Right-of-use asset	(181)	(286)
Goodwill	(1,022)	(774)
Total deferred tax assets, net	65,386	56,754
Less valuation allowance	(65,656)	(56,909)
Net deferred taxes	$ (270)	$ (155)

As of December 31, 2024, the Company had approximately $183.0 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, 2024, the Company has various research tax credits of $6.3 million that will begin to expire in 2038.

The income tax expense for the years ended December 31, 2024 and 2023 differed from the amounts computed by applying the U.S. federal income tax rate of 21% as follows:

	December 31,	
	2024	2023
Federal statutory rate	21.00 %	21.00 %
Warrants and related transaction costs	19.86	—
Acquired in-process research and development	(16.58)	—
Goodwill impairment	—	(2.60)
Stock compensation	(9.37)	(1.40)
State taxes	(0.26)	0.03
Research tax credit	1.17	0.47
Other	0.46	—
Valuation allowance	(16.61)	(17.54)
Effective income tax rate	(0.33)%	(0.04)%

The valuation allowance recorded by the Company as of December 31, 2024 and 2023, 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. In assessing the realization of deferred tax assets, management considers the reversal of deferred tax liabilities, as well as whether it is more likely than not that all or some portion of the deferred tax assets will not be realized. 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 has established deferred tax liabilities for indefinite lived intangible assets consisting of goodwill that are not amortized for financial reporting purposes, but are tax deductible and therefore amortized over 15 years for tax purposes. The Company has concluded that the resulting deferred tax liability will also have an indefinite life unless there is an impairment of the related assets (for financial reporting purposes), or the disposal of the business to which the assets relate.

Losses generated in years after 2017 will also have an indefinite life and will be available to offset 80 percent of any federal tax liability and will be available to offset many of the state deferred tax liabilities, subject to utilization limits. A portion of existing deferred tax assets will reverse in the future, potentially generating net operating losses that will also be available to offset a portion of the indefinite lived deferred tax liability. Based on the consideration of these facts, 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 full valuation allowance continues to be recorded against the Company's remaining deferred tax asset as of December 31, 2024 and December 31, 2023.

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, 2024, 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 $7.0 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.

AVTX-009

On March 27, 2024, Avalo obtained the rights to an anti-IL-1β mAb (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, 2024. There has been no cumulative expense recognized as of December 31, 2024 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, 2024. There has been no cumulative expense recognized as of December 31, 2024 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 $1.1 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 $1.1 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, 2024. Avalo has not recognized any cumulative expense under the agreement related to the milestone or royalties as of December 31, 2024. The Company will continue to monitor the milestones and royalties at each reporting period.

AVTX-008 Sanford Burnham Prebys License Agreement

On June 21, 2021, the Company entered into an Exclusive Patent License Agreement with Sanford Burnham Prebys Medical Discovery Institute (the "Sanford Burnham Prebys License Agreement") under which the Company obtained an exclusive license to a portfolio of issued patents and patent applications covering an immune checkpoint program (AVTX-008). Avalo is responsible for the development and commercialization of the program. Avalo is not currently pursuing the clinical development of AVTX-008 and is exploring strategic alternatives.

Under the terms of the Sanford Burnham Prebys License Agreement, the Company paid an upfront license fee of $0.4 million, as well as patent costs of $0.5 million, which we recognized within research and development expenses and within general and administrative expenses, respectively, in 2021. Additionally, Avalo pays a $40 thousand annual maintenance fee payable on the first anniversary of the effective date and each anniversary thereafter until the first commercial sale (of which Avalo has paid $0.1 million of annual maintenance fees as of the filing date of this Annual Report on Form 10-K). The Company is required to pay Sanford Burnham Prebys up to approximately $24.2 million based on achievement of specified development and regulatory milestones. Upon commercialization, the Company is required to pay Sanford Burnham Prebys sales-based milestone payments aggregating up to $50.0 million tied to annual net sales targets.

Additionally, the Company is required to pay Sanford Burnham Prebys royalties during a country-by-country royalty term equal to a tiered low-to-mid single digit percentage of annual net sales. Avalo is also required to pay Sanford Burnham Prebys tiered payments in which the low end and high end of the range fall on or between 10% and 20% of what Avalo receives from sublicensing its rights under the Sanford Burnham Prebys License Agreement, subject to certain exclusions.

The Sanford Burnham Prebys License Agreement remains in effect until the expiration of the royalty term, which with respect to each product and country, continues until the expiration, invalidation or abandonment of the last of the licensed patent rights.

Avalo may terminate the Sanford Burnham Prebys License Agreement at any time at its convenience upon providing at least ninety (90) days' prior written notice. Sanford Burnham Medical Discovery Institute may terminate the Sanford Burnham Prebys License Agreement for cause.

As disclosed above, Avalo paid the $0.4 million upfront fee, as well as total patent costs of $0.5 million and $0.1 million of annual maintenance fees. No further amounts have been paid related to the milestones, royalties or any other amounts under the agreement.

No expense related to milestones or royalties pursuant to the Sanford Burnham Prebys License Agreement was recognized in the year ended December 31, 2024. There has been no cumulative expense recognized as of December 31, 2024 related to the milestones or royalties under this license agreement other than the $0.4 million upfront fee incurred in 2021. 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, 2024. There has been $0.5 million of cumulative expense recognized as of December 31, 2024 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, 2024 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, 2024 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, 2024 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 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 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 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.

Aevi Merger Possible Future Milestone Payments

In the first quarter of 2020, the Company consummated its merger with Aevi, in which Avalo acquired the rights to quisovalimab, AVTX-006 and AVTX-007 (the "Merger" or the "Aevi Merger").

A portion of the consideration for the Aevi Merger included two future contingent development milestones worth up to an additional $6.5 million, payable in either shares of Avalo's common stock or cash, at the election of Avalo.

The first milestone was the enrollment of a patient in a Phase 2 study related to quisovalimab (for treatment of pediatric onset Crohn's disease), AVTX-006 (for treatment of any indication) or AVTX-007 (for treatment of any indication) prior to February 3, 2022, which would have resulted in a milestone payment of $2.0 million. The Company did not meet the first milestone prior to February 3, 2022. Therefore, no contingent consideration related to this milestone was recognized as of December 31, 2024 and no future contingent consideration will be recognized.

The second milestone was the receipt of an NDA approval for either AVTX-006 or AVTX-007 from the FDA on or prior to February 3, 2025, which would have resulted in a milestone payment of $4.5 million. The Company did not meet the second milestone prior to February 3, 2025. Therefore, no contingent consideration related to this milestone has been recognized as of December 31, 2024 and no future contingent consideration will be recognized.

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, 2024 and December 31, 2023. 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.

Karbinal Royalty Make-Whole Provision

In 2018, in connection with the acquisition of certain commercialized products, the Company entered into a supply and distribution agreement (the "Karbinal Agreement") with TRIS Pharma Inc. ("TRIS"). As part of the Karbinal Agreement, the Company had an annual minimum sales commitment, which is based on a commercial year that spans from August 1 through July 31, of 70,000 units through 2025. The Company was required to pay TRIS a royalty make whole payment ("Make-Whole Payments") of $30 for each unit under the 70,000 units annual minimum sales commitment through 2025.

As a part of the Aytu Transaction, the Company assigned all its payment obligations, including the Make-Whole Payments, under the Karbinal Agreement (collectively, the "TRIS Obligations") to Aytu. However, under the original license agreement, the Company could ultimately be liable for the TRIS Obligations to the extent Aytu fails to make the required payments. The future Make-Whole Payments to be made by Aytu are unknown as the amount owed to TRIS is dependent on the number of units sold.

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, 2024 and 2023:

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Nonclinical expenses	$ 570	$ 1,029
Clinical expenses	9,966	5,780
CMC expenses	5,106	1,855
Internal expenses:		
Salaries, benefits and related costs	6,164	3,576
Stock-based compensation expense	2,402	1,318
Other	229	226
	$ 24,437	$ 13,784

CORPORATE INFORMATION

Directors

Michael Heffernan, *Chairman of the Board*

Garry Neil, M.D., *Chief Executive Officer*

June Almenoff, M.D., Ph.D.

Mitchell Chan

Jonathan Goldman, M.D.

Aaron Kantoff

Gilla Kaplan, Ph.D.

Samantha Truex

Officers

Garry Neil, M.D., *Chief Executive Officer*

Mittie Doyle, M.D., FACR, *Chief Medical Officer*

Jennifer Riley, *Chief Strategy Officer*

Christopher Sullivan, *Chief Financial Officer*

Paul Varki*, Chief Legal Officer*

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Stock Listing

Avalo Therapeutics, Inc.'s common stock is listed on the Nasdaq Capital Market and quoted under the symbol "AVTX."

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