

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended December 31, 2025

OR

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

For the Transition Period from _____ to _____

Commission File Number 001-33650

LISATA THERAPEUTICS, INC.
(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

22-2343568
(I.R.S. Employer
Identification No.)

110 Allen Road, 2nd Floor, Basking Ridge, New Jersey
(Address of principal executive offices)

07920
(zip code)

Registrant's telephone number, including area code: 908-842-0100

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, par value \$0.001 per share	LSTA	The 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 15(d) of the Securities Exchange Act of 1934. 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 and 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 and post 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 definition of “large accelerated filer,” “accelerated filer,” and “smaller reporting company” in Rule 12b-2 of the Exchange Act:

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

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

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

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

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

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

The aggregate market value of the Registrant's voting and non-voting common stock held by non-affiliates of the Registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to June 30, 2025 (the last business day of the Registrant's most recently completed second fiscal quarter) was approximately \$23.6 million, computed by reference to the last sale price of \$2.90 for the common stock on the Nasdaq Capital Market reported for such date. Shares held by executive officers, directors and persons owning directly or indirectly more than 10% of the outstanding common stock have been excluded from the preceding number because such persons may be deemed to be affiliates of the Registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

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

Class	Outstanding as of March 12, 2026
Common stock, \$0.001 par value per share	9,032,291 shares

DOCUMENTS INCORPORATED BY REFERENCE

The following documents (or parts thereof) are incorporated by reference into the following parts of this Form 10-K: Certain information required in Part III of this Annual Report on Form 10-K is incorporated by reference from the Registrant's Proxy Statement for the 2026 Annual Meeting of Stockholders. Such Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the Registrant's fiscal year ended December 31, 2025.

All references in this Annual Report on Form 10-K to “we,” “us,” the “Company” and “Lisata” mean Lisata Therapeutics, Inc., including subsidiaries and predecessors, except where it is clear that the term refers only to Lisata Therapeutics, Inc. This Annual Report on Form 10-K contains forward-looking statements, which involve risks and uncertainties. The Company's actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those set forth under “Cautionary Note Regarding Forward-Looking Statements” and under “Risk Factors” and elsewhere in this Annual Report on Form 10-K.

TABLE OF CONTENTS

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

PART I	
ITEM 1. BUSINESS	6
ITEM 1A. RISK FACTORS	25
ITEM 1B. UNRESOLVED STAFF COMMENTS	63
ITEM 1C. CYBERSECURITY	63
ITEM 2. PROPERTIES	65
ITEM 3. LEGAL PROCEEDINGS	65
ITEM 4. MINE SAFETY DISCLOSURES	66
PART II	
ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES	67
ITEM 6. [RESERVED]	67
ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	68
ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	71
ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	71
ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	97
ITEM 9A. CONTROLS AND PROCEDURES	97
ITEM 9B. OTHER INFORMATION	98
ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS	98
PART III	
ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE	99
ITEM 11. EXECUTIVE COMPENSATION	101
ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS	102
ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE	102
ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES	102
PART IV	
ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES	103
ITEM 16. FORM 10-K SUMMARY	106

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report (this “Annual Report”) contains “forward-looking” statements within the meaning of the Private Securities Litigation Reform Act of 1995, as well as historical information. When used in this Annual Report, statements that are not statements of current or historical fact may be deemed to be forward-looking statements, including, without limitation, all statements related to any expectations of revenues, expenses, cash flows, earnings or losses from operations, cash required to maintain current and planned operations, capital or other financial items; any statements of the plans, strategies and objectives of management for future operations; any plans or expectations with respect to product research, development and commercialization, including regulatory approvals; any other statements of expectations, plans, intentions or beliefs; and any statements of assumptions underlying any of the foregoing. Without limiting the foregoing, the words “plan,” “project,” “forecast,” “outlook,” “intend,” “may,” “will,” “expect,” “likely,” “believe,” “could,” “anticipate,” “estimate,” “continue,” “target,” or similar expressions or other variations or comparable terminology are intended to identify such forward-looking statements, although some forward-looking statements are expressed differently. We remind readers that forward-looking statements are merely predictions and therefore inherently subject to uncertainties and other factors and involve known and unknown risks that could cause the actual results, performance, levels of activity or our achievements or industry results, to be materially different from any future results, performance, levels of activity or our achievements or industry results expressed or implied by such forward-looking statements. Factors that could cause our actual results to differ materially from anticipated results expressed or implied by forward-looking statements include, among others:

- the proposed acquisition of our company by Kuva Labs, Inc., including the anticipated time frame for completion of the transaction;
- our ability to obtain sufficient capital or strategic business arrangements to fund our operations and expansion plans, including collecting amounts owed to us under various licensing and other strategic arrangements, meeting our financial obligations under various licensing and other strategic arrangements, the funding of our clinical trials for product candidates, and the commercialization of the relevant technology;
- our ability to build and maintain the management and human resources infrastructure necessary to support the operation and/or growth of our business;
- our ability to continue as a going concern
- whether a market is established for our products and our ability to capture a meaningful share of this market;
- scientific, regulatory and medical developments beyond our control;
- our ability to obtain and maintain, as applicable, appropriate governmental licenses, accreditations or certifications or to comply with healthcare laws and regulations or any other adverse effect or limitations caused by government regulation of our business;
- whether any of our current or future patent applications result in issued patents, the scope of those patents and our ability to obtain and maintain other rights to technology required or desirable for the conduct of our business, and our ability to commercialize products without infringing upon the claims of third-party patents;
- whether any potential strategic or financial benefits of various licensing agreements will be realized;
- our ability to diversify our pipeline of development product candidates, which could include an acquisition, merger, business combination, in-license or other strategic transaction, and whether any of such efforts will result in us entering into or completing any transaction or that any such transaction, if completed, will add to shareholder value;
- the results of our development activities;
- our ability to complete our other planned clinical trials (or initiate other trials) in accordance with our estimated timelines due to delays associated with enrolling patients due to the novelty of the treatment, the size of the patient population, competition with other clinical trials for similar subjects, patient and/or investigator site availability and accessibility due to external macroenvironmental factors and the need of patients to meet the inclusion criteria of the trial or otherwise; and
- the extent to which any future public health crisis and their long-term effects may impact, directly or indirectly, our business, including our clinical trials and financial condition.

The factors discussed herein, including those risks described in “Item 1A. Risk Factors” and in our other periodic filings with the SEC, which are available for review at www.sec.gov, could cause actual results and developments to be materially different from those expressed or implied by such statements. All forward-looking statements attributable to us are expressly

qualified in their entirety by these and other factors. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date they were made. Except as required by law, we undertake no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

PART I

ITEM 1. BUSINESS.

Overview

Lisata Therapeutics, Inc. (together with its subsidiaries, the “Company”) is a clinical-stage pharmaceutical company dedicated to the discovery, development, and commercialization of innovative therapies for the treatment of solid tumors and other serious diseases. Our investigational product, certepetide (formerly known as LSTA1 or CEND-1), is designed to activate a novel uptake pathway (the C-end rule active transport mechanism) that allows co-administered or tethered (i.e., molecularly bound) anti-cancer drugs to target and penetrate solid tumors more effectively. Certepetide actuates this active transport system in a tumor-specific manner, resulting in systemically co-administered anti-cancer drugs more efficiently penetrating and accumulating in the tumor, while normal tissues are expected to remain unaffected. Certepetide has also been shown to modify the tumor microenvironment (“TME”) by reducing T-regulatory cells and augmenting cytotoxic T cells, thereby making tumors more susceptible to immunotherapies while also inhibiting the metastatic cascade (i.e., the spread of cancer to other parts of the body). We, our collaborators and other researchers have amassed and continue to amass significant non-clinical data demonstrating enhanced delivery of a range of existing and emerging anti-cancer therapies, including chemotherapeutics, immunotherapies, and RNA-based therapeutics. In addition, certain preclinical data using certepetide in combination with antibody drug conjugates (ADCs) has been generated as part of our research collaboration with Catalent. These data were presented at a scientific meeting during the fourth quarter of 2025. To date, certepetide has also demonstrated favorable safety, tolerability and activity in completed and ongoing clinical trials designed to enhance delivery of standard-of-care chemotherapy, with and without added immunotherapy, for pancreatic cancer. Certepetide is or has been the subject of several Phase 2 clinical studies globally in a variety of solid tumor types, including metastatic pancreatic ductal adenocarcinoma (mPDAC), cholangiocarcinoma, appendiceal cancer, colon cancer and glioblastoma multiforme in combination with a variety of anti-cancer regimens.

Our leadership team has amassed many decades of collective biopharmaceutical and pharmaceutical product development experience across a variety of therapeutic categories and at all stages of development from preclinical through to product registration and launch. Our goal is to develop and commercialize products that address important unmet medical needs.

Corporate Information

We incorporated in 1980 as a Delaware corporation, and our principal executive offices are located at 110 Allen Road, Second Floor, Basking Ridge, NJ 07920. Our telephone number is (908) 842-0100 and the corporate website address is www.lisata.com. Our website address in this Annual Report is included only as an inactive textual reference and is not intended to be an active link to our website. The information on the website is not incorporated by reference into this Annual Report.

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports, as well as other documents filed with the U.S. Securities and Exchange Commission (“SEC”), are available free of charge through the “Investors” section of the website as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. The public can obtain documents that are filed with the SEC at www.sec.gov.

This Annual Report includes the following trademark owned by us, CendR Platform[®]. This trademark is the property of Lisata. This Annual Report also includes other trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included herein are the property of their respective owners.

Recent Developments

Proposed Acquisition by Kuva Labs Inc.

On March 6, 2026, we entered into an Agreement and Plan of Merger (the “Merger Agreement”) with Kuva Labs Inc., a Delaware corporation (“Kuva”), and Kuva Acquisition Corp., a Delaware corporation and a wholly owned subsidiary of Kuva (“Purchaser”). Pursuant to the Merger Agreement, and upon the terms and subject to the conditions thereof, Purchaser will commence a tender offer (the “Offer”) to purchase all of our issued and outstanding shares of common stock, par value \$0.001 per share (the “Common Shares”), in exchange for (i) \$5.00 per Common Share, net to the seller in cash, without interest, but subject to any applicable withholding of taxes (the “Closing Amount”) plus (ii) one non-tradeable contingent value right (each, a “CVR”), which represents the contractual right to receive a contingent cash payment of \$1.00 per CVR (the “Milestone Payment”) if a New Drug Application or similar registration is filed or formally accepted for review by the FDA or any governmental authority in any jurisdiction with respect to any pharmaceutical product that contains or incorporates the product candidate referred to as of the date of the Merger Agreement as certepetide, alone or in combination with one or more other therapeutically active ingredients, including all formulations, dosages, or modes of delivery, for any indication or patient population prior to the earlier of (a) 11:59 p.m. New York City Time on the seventh (7th) anniversary of the Closing Date (as

defined in the Merger Agreement), and (b) termination of the CVR Agreement (the “Milestone”), in accordance with the terms and subject to the conditions of a contingent value rights agreement (the “CVR Agreement”) to be entered into with a rights agent selected by Kuva and reasonably acceptable to us (the Closing Amount plus one CVR, collectively, the “Offer Price”). If certain conditions are satisfied and the Offer is consummated, Kuva would acquire any remaining Common Shares for the Offer Price by a merger of Purchaser with and into us (the “Merger”).

The obligation of Kuva and Purchaser to consummate the Offer is subject to the satisfaction of customary conditions, including the condition that there be validly tendered, and not properly withdrawn, prior to the expiration of the Offer, that number of Shares that, together with the number of Shares, if any, then owned beneficially by Kuva and Purchaser (together with their wholly-owned subsidiaries), represents at least a majority of the Shares outstanding as of the consummation of the Offer. The obligation of Purchaser to consummate the Offer is also subject to other customary conditions. Consummation of the Offer is not subject to a financing condition.

Following the consummation of the Offer and subject to the terms and conditions of the Merger Agreement, Purchaser will merge with and into our company pursuant to the provisions of Section 251(h) of the General Corporation Law of the State of Delaware (the “DGCL”) as provided in the Merger Agreement, with our company being the surviving corporation. At the effective time of the Merger (the “Effective Time”), (i) each Common Share (other than (a) our treasury shares, (b) Shares owned by Kuva, Purchaser, us or any of their respective direct or indirect wholly-owned subsidiaries and (c) Shares held by stockholders who have properly demanded appraisal of such Shares in accordance with the DGCL (collectively, “Excluded Shares”)) will be cancelled and converted into the right to receive an amount in cash equal to the Offer Price, less applicable withholding of taxes (the “Common Merger Consideration”) and (ii) each of our issued and outstanding shares (the “Preferred Shares” and, together with the Common Shares, the “Shares”) of Series B Convertible Redeemable Preferred Stock, par value \$0.01 per share, other than Excluded Shares will be canceled and converted into the right to receive \$0.0005 per Preferred Share (which represents the Cash Amount and Milestone Payment per Preferred Share, on an as converted to Common Share basis) (the “Preferred Merger Consideration” and, together with the Common Merger Consideration, the “Merger Consideration”).

The Merger Agreement includes customary representations, warranties and covenants of the parties. The Merger Agreement also includes customary termination provisions for each of us and Kuva, subject, in certain circumstances, to the payment by us and Kuva of a termination fee equal to \$2,000,000.

The foregoing description of the Merger Agreement is only a summary of certain material provisions thereof, does not purport to be complete. The full text of the Merger Agreement is filed as Exhibit 2.1 to this Annual Report on Form 10-K.

The Offer and Merger are expected to close in the second quarter of 2026, subject to the terms of the Merger Agreement. Following completion of the transaction, we will become part of Kuva, a privately-held company, and our common stock will be delisted from the Nasdaq Capital Market (“Nasdaq”). We will also apply to deregister our common stock and cease to be a reporting company under the United States Securities Exchange Act of 1934, as amended. There can be no assurance that the Offer and the Merger will be consummated. Refer to Item 1A. “Risk Factors” for a summary of risks related to the proposed transaction.

Development Programs

Targeted Solid Tumor Penetration via CendR Active Transport

Many solid tumor cancers, including but not limited to pancreatic ductal adenocarcinoma (“PDAC”) and cholangiocarcinoma, are surrounded by dense fibrotic tissue, known as the tumor stroma. This stroma often limits the penetration of anti-cancer therapies including chemotherapy into the tumor and thus limits their efficacy. Emerging immunotherapies, including but not limited to checkpoint inhibitors and adoptive cell therapies (e.g., chimeric antigen receptor T cells (CAR-Ts)), also face challenges in effectively treating solid tumors. Many tumors exhibit an immunosuppressive TME, which suppresses a patient's immune system and can thus limit the effectiveness of immunotherapies and/or contribute to metastases. These factors, i.e., the combination of a dense stroma and an immunosuppressive TME, negatively impact the ability of many therapeutic agents to optimally treat these cancers.

To address the tumor stroma’s role as a key impediment to effective treatment, we make use of the C-end rule (“CendR”) active transport mechanism, a naturally occurring transport system. Our investigational drug, certepetide (a specific, proprietary *internalizing* R-G-D or iRGD peptide), activates this transport system in a tumor-specific manner (Sugahara, Science, 2010). Certepetide enables more selective and efficient uptake of systemically administered anti-cancer drugs resulting in more intratumoral drug accumulation. The overall expected result is enhanced anticancer activity without an increase in systemic adverse side effects. While it is possible to couple/tether or conjugate some anticancer drugs to certepetide, we believe that our initial approach of co-administration of certepetide with anti-cancer therapies is advantageous. Co-administration does not create a new chemical entity (“NCE”) with its attendant development and regulatory hurdles, thereby providing an anticipated

faster-to-clinic and faster-to-market product opportunity for a range of combination therapies. That said, an attractive life-cycle management strategy for certepetide would be to molecularly bind it to a variety of anti-cancer agents (as an alternative to co-administration), thereby creating new NCEs with the potential for distinct patent protection, compositionally or otherwise.

Certepetide has demonstrated favorable safety, tolerability, and activity to date in clinical trials enhancing the selective delivery of standard-of-care chemotherapies for mPDAC. Certepetide's cancer targeting characteristics may also enable emerging solid tumor treatment modalities to prove more effective. For example, preliminary results of certepetide in combination with both immunotherapy and chemotherapy are promising.

Certepetide as a treatment for solid tumor cancers in combination with other anti-cancer agents

Certepetide is an investigational drug that actuates the CendR active transport mechanism. Certepetide has been shown to modify the TME, making it less immunosuppressive and thereby making the tumor more susceptible to attack by the immune system while also inhibiting the metastatic cascade. It targets tumor vasculature, endothelial cells, tumor cells and some intratumoral immunosuppressive cells by its selective affinity for alpha-v beta-3 and alpha-v beta-5 integrins that are upregulated on these cells. Certepetide is a nine amino acid cyclic proprietary internalizing RGD ("iRGD") peptide that, once bound to these integrins, undergoes proteolytic cleavage to release a linear peptide fragment, called a CendR peptide fragment. After dissociation from the integrin receptor, the CendR peptide fragment then binds with high selectivity and affinity to an adjacent receptor, called neuropilin-1, also upregulated in solid tumors, to activate the novel uptake pathway that allows circulating anticancer drugs to more selectively and effectively penetrate solid tumors. The ability of certepetide and iRGD peptides to modify the TME to enhance delivery and efficacy of co-administered drugs has been demonstrated in many preclinical models in a range of solid tumors. We, our collaborators, and research groups around the world have published more than 400 scientific papers related to the benefits of iRGD peptides and the CendR pathway.

Clinically, certepetide has been the subject of multiple Phase 1 and Phase 2 trials. These studies include a Phase 1b/2a study in first line mPDAC patients. Study CEND1-201 was conducted in China by our former licensee, Qilu Pharmaceutical. Two dose levels of certepetide (1.6 and 3.2 mg/kg) were combined with SoC chemotherapy (gemcitabine and nab-paclitaxel). There were 55 patients in the study, 53 of whom were evaluable for efficacy. Twenty-five (25) patients were treated with 1.6 mg/kg certepetide and 28 patients with 3.2 mg/kg certepetide. In the 1.6 mg/kg certepetide group, partial response occurred in 11/25 (44.0%) patients, and stable disease occurred in 12/25 (48%) patients. In the 3.2 mg/kg certepetide group, partial response occurred in 11/28 (39.3%) patients, and stable disease occurred in 12/28 (42.9%) patients. The ORR was 41.5% for all doses. The ORR was 44.0% and 39.3% in the 1.6 mg/kg group and 3.2 mg/kg group, respectively. The DCR was 86.8% for all doses. The DCR in the 1.6 mg/kg group and 3.2 mg/kg group was 92.0% and 82.1%, respectively. The median PFS was 5.82 months for all doses combined. The median PFS was 7.36 months and 5.75 months in the 1.6 mg/kg group and 3.2 mg/kg group, respectively. The median OS was 11.10 months for all doses combined. The median OS was 10.35 months and 11.10 months in 1.6 mg/kg group and in 3.2 mg/kg group, respectively. The adverse event profile at both dose levels was similar to that for SoC alone. Qilu has informed us that they completed enrollment in the Phase 2 CEND1-202 study (n=96) in first line mPDAC in combination with SoC gemcitabine and nab-paclitaxel. We have not received a final clinical study report from the trial nor expect to, given that rights to certepetide have reverted to Lisata based on a mutual license termination agreement with Qilu, and there is no obligation on Qilu's part that such a report is to be received by Lisata. Additionally, since Qilu was the sponsor of the aforementioned Phase 2 trial, Lisata does not own rights to any of the data.

Certepetide was also the subject of a Phase 2b trial in first-line mPDAC patients, the ASCEND trial. We collaborated with the academic sponsor of the ASCEND trial, the Australasian Gastrointestinal Clinical Trials Group (AGITG) along with the University of Sydney to conduct the study at 25 sites in Australia and New Zealand. The Phase 2 double-blind, randomized (2:1), placebo-controlled, multi-center ASCEND trial evaluated certepetide in combination with SoC chemotherapy (gemcitabine and nab-paclitaxel) for the treatment of mPDAC. The original ASCEND protocol included one dosing scheme for certepetide. Following the acquisition of Cend Therapeutics and, by extension, certepetide in September 2022, Lisata collaborated with AGITG to amend the protocol to ensure it respected international regulatory standards. Thus, endpoints typically recognized by regulators as primary in registration studies and more effective in guiding next stages of clinical development (e.g., overall survival), were added. The amended protocol was designed to assess the efficacy of two different dosing regimens of certepetide in two separate cohorts: Cohort A, with 95 patients received a single intravenous (IV) dose of certepetide 3.2 mg/kg or placebo in combination with SoC, and Cohort B, with 63 patients received two IV doses of certepetide 3.2 mg/kg or placebo administered 4 hours apart in combination with SoC. The preliminary data from Cohort A were reported at the ASCO GI meeting on January 24, 2025, demonstrating a median overall survival (mOS) of 12.68 months for the certepetide treated group, compared to 9.72 months for the placebo treated group. Despite a numerical trend in 6-month PFS favoring the certepetide treatment group, no significant improvement in median PFS was observed (mPFS of 5.5 months in both groups). However, the objective response rate (ORR) benefit is positive with 4/65 (6.2%) complete responses in the certepetide treated group, compared to 0/28 (0%) the placebo treated group. The preliminary data from Cohort B were presented at the ESMO-GI meeting in July 2025, demonstrating a six-month progression-free survival ("6MPFS") of 60.8% for the certepetide-

treated group, whereas the 6MPFS in the placebo-treated group was 25%. Median progression-free survival (“mPFS”) was 7.5 months for the certepetide-treated group and 4.7 months for the placebo-treated group. Objective response rate (“ORR”) was 45.2% for the certepetide-treated group and 19% for the placebo-treated group. Median overall survival (“mOS”) was 10.32 months for the certepetide-treated group compared to 9.23 months for the placebo-treated group. A comparison of the preliminary data from Cohorts A and B indicated that the addition of two doses of certepetide (Cohort B regimen) to SoC chemotherapy resulted in a clinically meaningful improvement in both PFS and ORR for patients with mPDAC. We believe that these preliminary clinically significant findings provide compelling support for the continued and expedited investigation of certepetide as a novel therapeutic agent for the treatment of metastatic pancreatic cancer. The adverse event profile of Cohorts A and B remain similar in subjects treated with certepetide compared to placebo, confirming previous observations of certepetide’s benign safety profile. Additional data from Cohorts A and B was presented at the ESMO annual meeting in October 2025 with a final study report of the ASCEND study anticipated to be prepared and made available to Lisata in 2026.

Additionally, certepetide remains the subject of ongoing clinical trials being conducted globally in a variety of solid tumor types and in combination with several chemotherapy and immunotherapy anti-cancer regimens. These include three investigator-initiated trials: a Phase 2a trial in glioblastoma multiforme (GBM) in patients with newly diagnosed GBM, a Phase 1b/2a trial (iLSTA) in locally advanced non-resectable pancreatic ductal adenocarcinoma, and a Phase 1b/2a trial (CENDIFOX) in pancreatic, colon, and appendiceal cancers. Data announcements and final study reports from these investigator-initiated trials are entirely within the purview of the academic sponsors. Lisata’s Phase 2a BOLSTER trial, evaluating a single 3.2 mg/kg dose of certepetide in combination with standards of care in first and second-line cholangiocarcinoma completed and demonstrated no evidence of benefit or increase in adverse events when a single 3.2 mg/kg dose of certepetide was added to standard of care.

Technology Collaboration and Out-Licensing Opportunities

Pancreatic Cancer & Advanced Solid Tumors (certepetide: CendR Platform®)

Our investigational drug candidate from the CendR Platform®, certepetide, holds broader potential to be combined as a co-administration treatment with an array of anti-cancer and diagnostic agents to benefit solid tumor cancer patients and we seek to collaborate with chemotherapy, targeted and immuno-therapy developers. The Company plans to enter partnerships to exploit the CendR Platform® for applications to enhance or enable effective diagnosis and treatment of solid tumor cancers across a range of treatment modalities. These include but are not limited to nucleic acid-based treatments such as antisense, siRNA, mRNA and gene editing approaches, immunotherapies such as adoptive cell immunotherapy as well as immune checkpoint inhibitors, and additional targeted therapy treatments for solid tumor cancer applications.

Intellectual Property Platform

Our developed and owned certepetide and CendR Platform® patent portfolio comprises the following:

- a. Two pending patent applications in the United States;
- b. Thirteen pending patent applications outside the United States; and
- c. Pending claims covering, inter alia, methods for reducing the volume of a tumor using certepetide in combination with at least one anti-cancer agent or therapy; methods of treating pancreatic cancer using certepetide in combination with gemcitabine and/or nab-paclitaxel and methods of treating cancer in combination with chemotherapeutic and immunotherapeutic agents.

Product Opportunity for Pancreatic ductal adenocarcinoma (PDAC)

In the United States, there are approximately 67,000 new cases of pancreatic cancer diagnosed annually. Outside of the United States, there are an additional 498,000 annual pancreatic cancer diagnoses. PDAC accounts for more than 80% of all pancreatic cancer cases, so worldwide, nearly 452,000 annual incidences of PDAC are diagnosed. Further, PDAC is one of the most aggressive and lethal malignancies, with a 5-year survival rate of 13%, resulting in approximately 52,000 deaths annually in the United States alone. Moreover, on a global scale, pancreatic cancer results in over 466,000 deaths per year.

Seasonality

We do not believe that our operations are seasonal in nature.

Government Regulation

The healthcare industry is one of the most highly regulated industries in the United States and abroad. Various governmental regulatory authorities, as well as private accreditation organizations, oversee and monitor the activities of individuals and businesses engaged in the development, manufacture and delivery of healthcare products and services. The following is a general description of certain current laws and regulations that are relevant to our business:

U.S. Government Regulation

Premarket Review and Approval of Pharmaceutical Products in the United States

Pharmaceutical products are subject to extensive pre-market and post-market regulation by the U.S. Food and Drug Administration (the “FDA”) and other global agencies. For example, the Federal Food, Drug, and Cosmetic Act (“FD&C Act”) and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products intended for therapeutic uses. Before being marketed in the United States, pharmaceuticals must be reviewed and approved by the FDA via a New Drug Application (“NDA”).

Failure to comply with applicable requirements may subject a company to a variety of administrative or judicial sanctions, by the FDA and other global agencies, such as the issuance of a clinical hold, refusal to approve pending NDAs or NDA supplements, withdrawal of an approval, issuance of warning letters and other types of enforcement letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice, or DOJ, or other global governmental entities. Under certain circumstances, individual members of company management may also be subject to civil or criminal penalties related to company violations of applicable legal requirements.

An applicant seeking approval to market and distribute a new pharmaceutical product in the United States typically must undertake the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the good laboratory practice or GLP regulations;
- submission to a health authority of an investigational new drug application (“IND”), which includes the detailed clinical protocol and must take effect before human clinical trials can commence;
- approval of the clinical trial protocol and the sponsor's safeguards for human subjects by one or more institutional review boards, or “IRBs,” depending on the numbers of clinical sites and other features of the study design, before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or “GCPs,” to establish the safety and efficacy of the proposed drug product for each proposed indication for which regulatory approval is sought;
- satisfactory completion of regulatory audits of the Sponsor, clinical research organizations, or clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- preparation and submission to a health authority of an NDA;
- review of the product by a regulatory advisory committee, where appropriate or if applicable, as determined by the FDA at its discretion;
- satisfactory completion of one or more regulatory inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with the regulations establishing current Good Manufacturing Practices, or “cGMPs,” and to assure that the facilities, methods and controls used for the manufacture, processing and packing of the drug product are adequate to preserve the product’s identity, strength, quality and purity; and
- payment of applicable user fees and securing regulatory approval of the NDA.

Satisfaction of regulatory pre-market approval requirements typically takes many years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. Moreover, submission of an IND may not result in authorization to initiate a clinical trial if the FDA raises concerns or questions about the design of the clinical trial or the non-clinical or manufacturing information supporting it, including concerns that human research subjects will be exposed to unreasonable health risks. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. After a trial is initiated, the FDA or the IRB overseeing the trial may order the temporary or permanent discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial is not being conducted in accordance with applicable requirements or presents an unacceptable risk to the clinical trial patients.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of one or more qualified investigators. Clinical trials must be conducted in compliance with federal regulations and GCPs, which are meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors. In addition, sponsors of most clinical trials involving regulated products, including drugs and biologics, are required to register and disclose certain clinical trial information on a public registry and results database managed by the National Institutes of Health called [ClinicalTrials.gov](https://clinicaltrials.gov). Registration information that must be submitted includes information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial. Sponsors are also obligated to disclose the results of their clinical trials after completion. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs. Failure to comply with applicable clinical trial registration or results reporting obligations can result in civil monetary penalties or the withholding of grant funds from a federally funded grantee.

Clinical trials for marketing approval are typically conducted in three sequential phases, but the phases may overlap or may be combined. Under certain circumstances, a fourth post-approval phase may be required.

- *Phase I:* Trials in this phase are initially conducted in a limited population of healthy volunteers to test the product candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients, such as cancer patients, when the investigational drug is too toxic to be ethically given to healthy individuals.

- *Phase 2:* These clinical trials are generally conducted in a limited patient population to determine the presence and approximate magnitude of therapeutic effect of the product candidate for specific targeted indications and to identify appropriate therapeutic dose and dose frequency as well as any corresponding additional possible adverse effects and safety risks. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- *Phase 3:* These are commonly referred to as pivotal or registration studies. When Phase 2 evaluations demonstrate that a dose range of the product candidate is effective and has an acceptable safety profile, Phase 3 clinical trials are typically undertaken in a larger patient population to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple and geographically dispersed clinical trial sites.
- *Phase 4:* In some cases, the FDA may condition approval of an NDA for a product candidate on the sponsor's agreement to conduct additional clinical trials after NDA approval. In other cases, a sponsor may voluntarily carry out additional trials post approval to gain more information about the drug product.

Congress amended the FD&C Act in 2022 to require sponsors of a Phase 3 clinical trial, or other “pivotal study” of a new drug to support marketing authorization, to design and submit a diversity action plan for such clinical trial. The action plan must include the sponsor’s diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. Sponsors must submit a diversity action plan to the FDA by the time the sponsor submits the relevant clinical trial protocol to the agency for review. The FDA may grant a waiver for some or all of the requirements for a diversity action plan. If the FDA objects to a sponsor’s diversity action plan or otherwise requires significant changes to be made, it could delay initiation of the relevant clinical trial.

Submission and FDA Review of an NDA

Assuming successful completion of all required testing in accordance with applicable regulatory requirements, the results of the preclinical studies and clinical trials, together with detailed information relating to the product’s chemistry, manufacture, controls and proposed labeling, among other things, are submitted as part of an NDA seeking approval to market the drug product for one or more indications. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety, efficacy, and reliable manufacturing of the product candidate for its intended use(s) to the satisfaction of the FDA. Approval of the NDA is required before marketing of the product may begin. The cost of preparing and submitting an NDA is substantial. NDA submissions are additionally subject to a substantial application user fee, unless a fee waiver or reduction applies. Reduced or waived fees are available in certain circumstances, such as where a waiver is necessary to protect the public health, where the fee would present a significant barrier to innovation, or where the applicant is a small business submitting its first human therapeutic application for review. The FD&C Act also imposes an annual program fee for marketed prescription drug products. These fees are typically adjusted annually.

The FDA has 60 days after submission of an NDA to conduct a preliminary review in order to determine whether the application will be accepted for filing based on the Agency's threshold determination that the application is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. If the application is not sufficiently complete, the regulator may issue a Refusal to File, or RTF, letter. In this event, the application must be resubmitted with the additional information and the resubmitted application is also subject to review before FDA accepts it for filing. FDA has ten months from the filing date in which to complete its review of a new molecular-entity (“NME”) NDA and respond to the applicant, and six months from the filing date of an NME NDA designated for priority review. For non-NME NDAs, the review goals are ten months from the date of receipt for a standard application and six months from the date of receipt for a priority submission. The FDA does not always meet its goal dates for standard and priority NDAs, and the review process is often extended by FDA requests for additional information or clarification. In addition, if a sponsor submits a major amendment to a filed NDA at any time during the review cycle, the FDA may extend the goal dates for review.

Before approving an NDA, the FDA will typically inspect one or more clinical trial sites to ensure compliance with GCPs. Additionally, the FDA will also inspect the facility or the facilities at which the drug is manufactured. These pre-approval inspections cover all facilities associated with an NDA submission, including drug component manufacturing (such as active pharmaceutical ingredients), finished drug product manufacturing, and control testing laboratories. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with applicable cGMP requirements and are adequate to assure consistent production of the drug product within required specifications and the NDA. To ensure cGMP and GCP compliance by its employees and third-party contractors, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production and quality control.

During its review of an NDA, the FDA may also refer applications for novel drug products, or drug products that present

difficult questions of safety or efficacy, to an advisory committee of independent clinicians and other scientific experts for review, evaluation, and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee but will carefully consider them. Data from clinical trials are not always conclusive, and FDA or its advisory committee may interpret data differently than the NDA applicant interprets the same data. FDA may also re-analyze the clinical trial data, which could result in extensive discussions between FDA and the applicant during the review process.

After the FDA fully evaluates the NDA and the relevant manufacturing facilities, the FDA will issue either an approval letter or a complete response letter (“CRL”). A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. In September 2025, the FDA began publishing CRLs soon after issuing them to the respective sponsors, breaking with long standing agency tradition of publishing CRLs with approval documentation after the product is approved. If a CRL is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmitted NDA, the FDA will issue an approval letter to the applicant. FDA has committed to reviewing such resubmissions in response to an issued CRL in either two or six months depending on the type of information being provided to address the deficiencies in the CRL. Even with the submission of this additional information, however, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

Even if the FDA approves a drug product for marketing, it may limit the approved indications for use for the product; require that contraindications, warnings or precautions be included in the product labeling; require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety after approval; require testing and surveillance programs to monitor the product after commercialization; or impose other conditions, including distribution restrictions or other risk management mechanisms, such as a risk evaluation and mitigation strategy or “REMS.” The FDA may also limit further marketing of a product or withdraw the marketing approval, based on results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications or patient populations, making certain types of manufacturing changes or seeking to make additional labeling claims, are subject to further testing requirements and FDA review and approval.

One potential condition of approval is that the FDA may require an applicant to develop a REMS if it determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks and to assure the safe use of the product. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity. REMS requirements are tailored to the specific risk/benefit profile of a drug and can include requirements such as medication guides for patients, detailed communication plans for healthcare professionals, and elements to assure safe use, or “ETASU.” ETASU may include, but is not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, restricted distribution, and the use of patient registries. The FDA may require a REMS as a condition of approval or may add such a requirement at any point post-approval if it becomes aware of a serious risk associated with use of the product. The requirement for a REMS and the specific components that are involved can materially affect the potential market and profitability of an approved drug product. If the FDA concludes that a REMS plan is needed, the sponsor of the NDA must submit a proposed REMS plan to the FDA for review. The FDA will not approve an NDA without a REMS, if required.

Expedited Review Programs (Fast Track, Breakthrough and Priority Review Designations)

The FDA is authorized to facilitate the development and expedite the review of certain drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment, and which demonstrate the potential to address unmet medical needs for the condition. For example, under the FDA's Fast Track Program, the sponsor of an IND for a drug candidate may request that the FDA designate the drug candidate for a specific indication as a Fast Track drug concurrent with, or after, the submission of the IND for the drug candidate. The FDA must determine if the drug candidate qualifies for Fast Track designation within 60 days of receipt of the sponsor's request. In addition to other benefits such as the ability to engage in more frequent interactions with the FDA, the FDA may initiate review of sections of a Fast Track drug's NDA before the application is complete. This “rolling review” is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees.

In addition, drug product candidates may be designated by FDA as “breakthrough therapies” upon a request made by the IND sponsors. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies may

also be eligible for accelerated approval of their respective marketing applications. FDA must take certain actions with respect to breakthrough therapies, such as holding timely meetings with and providing advice to the product sponsor, intended to expedite the development and review of an application for approval of a breakthrough therapy.

FDA may designate a product for priority review if it is a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. FDA determines at the time that the marketing application is submitted, on a case-by-case basis, whether the proposed drug represents a significant improvement in treatment, prevention or diagnosis of disease when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten FDA's goal for taking action on a marketing application from ten months to six months for an NME NDA from the date of filing.

In 2025, the FDA created a new voucher program called the Commissioner's National Priority Voucher ("CNPV") with the goal of radically expediting the drug and biological product review and approval process. The agency may award a CNPV to a company or a specific product candidate that demonstrates alignment with certain national health priorities. The FDA aims to take action on a marketing application for which a CNPV is used within one to two months after the filing date.

Even if a product qualifies for one or more of these programs, FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore none of these programs changes the standards for approval and may not ultimately expedite the development or approval process.

Accelerated Approval Pathway

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval from FDA and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. FDA may also grant accelerated approval for such a drug when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, FDA may require that a sponsor of a drug receiving accelerated approval perform post-marketing clinical trials to verify and describe the predicted effect on IMM or other clinical endpoint, and the product may be subject to expedited withdrawal procedures. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval. Further, all promotional materials for product candidates being considered and approved under the accelerated approval program are subject to prior review by the FDA.

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

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

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. In addition, as part of the Consolidated Appropriations Act for 2023, Congress provided FDA additional statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. As a result of these recent amendments to the FD&C Act, the agency now generally requires a sponsor of a product granted accelerated approval to have a confirmatory

trial underway prior to approval. The sponsor must also submit progress reports on a confirmatory trial every six months until the trial is complete, and such reports will be published on the FDA's website. Failure to conduct required post-approval studies, or to confirm the predicted clinical benefit of the product during post-marketing studies, allows the FDA to withdraw approval of the drug. Congress also recently amended the law to give FDA the option of using expedited procedures to withdraw product approval if the sponsor's confirmatory trial fails to verify the claimed clinical benefits of the product. Prior to the recent statutory amendments enacted by Congress, several oncology sponsors voluntarily withdrew specific indications for their drug products that were being marketed pursuant to accelerated approval, and the FDA's Oncology Center of Excellence launched an initiative called Project Confirm, aimed at promoting transparency in the area of accelerated approvals for oncology indications. Scrutiny of the accelerated approval pathway is likely to continue in the coming years and may lead to further legislative and/or administrative changes in the future.

Pediatric Information

Under the Pediatric Research Equity Act ("PREA"), NDAs or supplements to NDAs must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. Sponsors must also submit pediatric trial plans and those plans must contain an outline of the proposed pediatric trial or trials the applicant plans to conduct, including trial objectives and design, any deferral or waiver requests and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time. The FDA may grant full or partial waivers or deferrals by age group for submission of data. In addition, FDA is required to send a PREA Non-Compliance letter to sponsors who have failed to submit their pediatric assessments required under PREA, have failed to seek or obtain a deferral or deferral extension or have failed to request approval for a required pediatric formulation, and FDA publicly posts such PREA Non-Compliance letters and sponsor's response. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation, although the FDA has taken steps to limit what it considers abuse of this statutory exemption in PREA by announcing that it does not intend to grant any additional orphan drug designations for rare pediatric subpopulations of what is otherwise a common disease.

The FDA Reauthorization Act of 2017 introduced a provision regarding required pediatric studies. Under this statute, for product candidates intended for the treatment of an adult cancer which are directed at molecular targets that the FDA determines to be substantially relevant to the growth or progression of one or more pediatric cancers, original application sponsors must submit, with the marketing application, reports from molecularly targeted pediatric cancer investigations designed to yield clinically meaningful pediatric study data, gathered using appropriate formulations for each applicable age group, to inform potential pediatric labeling. The FDA may, on its own initiative or at the request of the applicant, grant deferrals or waivers of some or all of this data, as above. Unlike PREA, orphan products for oncology indications are not exempt from this requirement.

The Best Pharmaceuticals for Children Act ("BPCA") provides approved NDA holders a six-month extension of any exclusivity that attaches to the end of all existing marketing exclusivities and listed patents for the drug. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's written request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers. FDA's issuance of a written request for pediatric studies does not require the sponsor to undertake the described trials.

Congress periodically considers enacting new incentives or mandates applicable to pediatric drug development, and the regulatory requirements applicable to pediatric drug developers may change in the future. For example, in February 2026, bipartisan legislation was signed into law and grants FDA authority to assess penalties against companies that do not complete required pediatric studies.

Orphan Drugs

Under the Orphan Drug Act, the FDA may designate a candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally a disease or condition that affects either (i) fewer than 200,000 individuals in the United States or (ii) more than 200,000 individuals in the United States but there is no reasonable expectation that the cost of developing and making such a product available for this type of disease or condition will be recovered from sales in the United States from the product. Orphan drug designation must be requested by an applicant before submitting an NDA for the relevant drug candidate.

After FDA grants orphan drug designation, it will publicly disclose the generic identity of the drug candidate and its potential orphan use. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product with orphan status receives the first regulatory approval for the disease or condition for which it has such designation, the product generally will receive orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances (such as showing of clinical superiority to the drug with orphan exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care). However, a competitor may receive regulatory approval for a different product (i.e., a different therapeutic agent from the orphan drug) for the same indication for which the orphan product has exclusivity and may obtain approval for the same product (i.e., the same therapeutic agent as the orphan drug) but for a different indication. If a designated orphan drug ultimately receives marketing approval for an indication broader than what was described in its orphan drug designation request, it may not be entitled to exclusivity under the Orphan Drug Act. Recent court cases have challenged FDA's approach to determining the scope of orphan drug exclusivity; however, at this time the Agency continues to apply its long-standing interpretation of the governing regulations and has stated that it does not plan to change any orphan drug implementing regulations.

Among the other benefits of orphan drug designation, the sponsor receives a waiver of the NDA application user fee and is eligible for tax credits for certain research. The current tax credit regulation allows companies to claim up to 25% of the qualified clinical testing expenses in the current year and three prior years to offset their investment in rare (orphan) conditions.

Rare Pediatric Disease Designations

Under Section 529 of the FD&C Act, FDA can grant a Rare Pediatric Disease Designation ("RPDD") to a drug intended to prevent or treat a rare pediatric disease, defined as a serious or life-threatening disease that primarily affects patients from birth to 18 years or age and with a prevalence of less than 200,000 in the United States. RPDD requests should be made by the sponsor at any time prior to the submission of an NDA.

FDA can award priority review vouchers ("PRVs") to sponsors of rare pediatric disease product applications that meet certain criteria. Under this program, a sponsor who receives an approval for a drug that has been granted an RPDD may qualify for such a voucher, which can be redeemed to receive a priority review of a subsequent marketing application for a different product. Upon submitting a marketing application with a PRV, the sponsor is required to pay a separate user fee that is assessed in addition to the typical application user fee (if no waiver or exemption applies); the fee for redeeming a PRV is also adjusted each fiscal year. For fiscal year 2026 that additional user fee is approximately \$2.0 million.

A PRV is transferable and may be sold to other companies who wish to obtain a priority review for a future new drug or biological product marketing application.

The Consolidated Appropriations Act for 2026, which was signed into law on February 3, 2026, extended the FDA's authority to grant Rare Pediatric Disease Priority Review Vouchers until September 30, 2029. The legislation also amended the FD&C Act to remove language imposing a deadline for a drug developer to have its product pre-designated by the FDA as intended for a "rare pediatric disease."

Post-Approval Requirements

Following approval, drug products and their manufacturers are subject to pervasive and continuing regulation by the FDA including, among other things, requirements relating to monitoring and recordkeeping, reporting of adverse experiences with the product, product sampling and distribution restrictions, and complying with advertising and promotion requirements, which include restrictions on promoting drugs for unapproved uses or patient populations (i.e., "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. If there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the applicant to develop additional data or conduct additional non-clinical studies and clinical trials.

Further, drug manufacturers and other entities involved in the manufacture of approved drugs are required to register their facilities with the FDA and state agencies and are subject to periodic unannounced inspections for compliance with cGMP requirements. Changes to the manufacturing process, specifications or container closure system for an approved drug are strictly regulated and often require prior regulatory approval before being implemented. Regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and

others involved in the product's manufacturing process. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance and ensure ongoing compliance with other statutory requirements of the FD&C Act.

Even after a new drug approval is granted, the FDA may withdraw that approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. If a previously unknown problem, including adverse events of unanticipated severity or frequency, or with manufacturing processes, is discovered or the manufacturer fails to comply with regulatory requirements, the FDA may require revisions to the approved labeling to add new safety information; may impose additional post-market studies or clinical trials to assess new safety risks; or may impose distribution or other restrictions under a REMS program. Other potential consequences of regulatory non-compliance include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the regulator to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties;
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal healthcare programs; and
- mandated modification of promotional materials and labeling and the issuance of corrective information.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. More recently, the Drug Supply Chain Security Act, or DSCSA, was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States. The DSCSA mandates resource-intensive traceability and verification obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers. The DSCSA also replaced certain provisions from the PDMA pertaining to wholesale distribution of prescription drugs with a more comprehensive statutory scheme, requiring uniform national standards for wholesale distribution and, for the first time, for third-party logistics providers. In February 2022, the FDA released proposed regulations to amend the existing national standards for licensing of wholesale drug distributors by the states (which had been promulgated under the PDMA); to establish new minimum standards for state licensing third-party logistics providers; and to create a federal system for licensure for use in the absence of a state program, each of which is mandated by the DSCSA. From time to time, additional new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. It is impossible to predict whether further legislative or regulatory changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Other Healthcare Laws and Regulations

If our product candidates are approved in the United States, we will have to comply with various U.S. federal and state laws, rules and regulations pertaining to healthcare fraud and abuse, including but not limited to anti-kickback laws. Violations of the fraud and abuse laws are punishable by criminal and civil sanctions, including, in some instances, exclusion from participation in federal and state healthcare programs, including Medicare and Medicaid. Other federal and state laws and regulations that could directly or indirectly affect our ability to operate the business and/or financial performance include:

- laws and regulations administered by the United States Department of Health and Human Services, including the Office for Human Research Protections and the Office of Inspector General;
- state laws and regulations governing human subject research;
- federal and state coverage and reimbursement laws and regulations, including laws and regulations administered by the Centers for Medicare & Medicaid Services (“CMS”) and state Medicaid agencies;

- the federal Anti-Kickback Law and similar state laws and regulations;
- the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”) and similar state laws and regulations;
- the federal transparency requirements under the Physician Payments Sunshine Act that require manufacturers of FDA-approved drugs, devices, biologics and medical supplies covered by Medicare or Medicaid to report, on an annual basis, to the Department of Health and Human Services information related to payments and other transfers of value physicians, teaching hospitals, and certain advanced non-physician healthcare practitioners and physician ownership and investment interests;
- Occupational Safety and Health Administration requirements; and
- state and local laws and regulations dealing with the handling and disposal of medical waste.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines, or the relevant compliance guidance promulgated by the federal government, in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures to the extent that those laws impose requirements that are more stringent than the Physician Payments Sunshine Act. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Violations of the fraud and abuse laws, or other healthcare laws, are punishable by criminal and civil sanctions, including, in some instances, the possibility of exclusion from participation in federal and state healthcare programs, (including Medicare and Medicaid), and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties also may be imposed upon executive officers and employees, including criminal sanctions against executive officers under the so-called “responsible corporate officer” doctrine, even in situations where the executive officer did not intend to violate the law and was unaware of any wrongdoing. Given the penalties that may be imposed on companies and individuals if convicted, allegations of such violations often result in settlements even if the company or individual being investigated admits no wrongdoing. Settlements often include significant civil sanctions, including fines and civil monetary penalties, and corporate integrity agreements. In addition, private individuals have the ability to bring similar actions under some of the fraud and abuse laws. Further, federal and state laws that require manufacturers to make reports on pricing and marketing information could subject us to penalty provisions.

Coverage, Pricing, and Reimbursement

Sales of our drug products, if approved, will depend, in part, on the extent to which the costs of our products will be covered by third-party payors, such as government healthcare programs, private health insurers, managed healthcare providers, and other organizations. These third-party payors are increasingly challenging drug prices and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other therapies, they may not cover our products, if approved as a benefit under their plans or, even if they do provide coverage, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

Significant uncertainty exists as to the reimbursement status for newly approved prescription products, including coding, coverage and payment. Sales of any products for which we obtain marketing approval will depend in part on coverage and adequate payment from third-party payors. There is no uniform policy requirement for coverage and reimbursement for prescription products among third-party payors in the United States; therefore, coverage and reimbursement for prescription products can differ significantly from payor to payor.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. A payor’s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by third-party payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. In the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but they also have their

own methods and approval process apart from Medicare coverage and reimbursement determinations. One third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product.

Accordingly, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products, if approved, to each payor separately, with no assurance that coverage and adequate payment will be applied consistently or granted at all. The process for determining whether a payor will cover and how much it will reimburse a product may be separate from the process of seeking approval of the product or for setting the price of the product. Even if reimbursement is provided, market acceptance of our products, if approved, may be adversely affected if the amount of payment for such products proves to be unprofitable for healthcare providers or less profitable than alternative treatments or if administrative burdens make the products less desirable to use.

Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drug products have been a focus in this effort. For example, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. In August 2022, President Biden signed into the law the Inflation Reduction Act of 2022, or the IRA, which includes (among other things) multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. For example, under the IRA, a manufacturer of drug products covered by Medicare Parts B or D must pay a rebate to the federal government if their drug product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, CMS will negotiate drug prices annually for a select number of single source Part D drugs without generic competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new authorities, announcing the first round of negotiated prices for the first 10 products in August 2024, which will become applicable for payment year 2026. The second round of negotiated prices for 15 drug products was announced in November 2025. However, the IRA's impact on the pharmaceutical industry in the United States remains uncertain, in part because multiple large pharmaceutical companies and other stakeholders (e.g., the U.S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. Those lawsuits are currently ongoing.

Separately, the Trump Administration announced the creation of a government website called TrumpRx, which will allow consumers to purchase certain drugs at reduced prices as negotiated between the drug manufacturers and the administration. As of December 2025, the Trump Administration secured deals with five major drug manufacturers to offer certain drugs at most-favored-nation prices.

We expect that federal, state and local governments in the United States will continue to consider legislation directed at lowering the total cost of healthcare. Individual U.S. states have increasingly passed legislation and implemented 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. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmacy benefit managers ("PBMs") and other members of the healthcare and pharmaceutical supply chain, an important decision that has led to more aggressive efforts by states in this area. During the current congressional session, numerous PBM reforms are being considered in both the Senate and the House of Representatives; they include diverse legislative proposals such as eliminating rebates; divorcing service fees from the price of a drug, discount, or rebate; prohibiting spread pricing; limiting administrative fees; requiring PBMs to report formulary placement rationale; promoting transparency. The Federal Trade Commission in mid-2022 also launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. Significant efforts to change the PBM industry as it currently exists in the United States may affect the entire pharmaceutical supply chain and the business of other stakeholders, including medical product developers like us.

It is uncertain whether and how future legislation or regulatory changes could affect prospects for our product candidates or what actions federal, state, or commercial payors for pharmaceutical products may take in response to any such healthcare reform proposals or legislation. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures reforms may prevent or limit our ability to generate revenue, attain profitability or commercialize our product candidates.

Patent Term Extension

A patent claiming a prescription drug for which FDA approval is granted may be eligible for a limited patent term extension under the FD&C Act, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review provided that certain statutory and regulatory requirements are met. The length of the patent term extension is related to the length of time the drug is under regulatory review while the patent is in force. The restoration period granted on a patent covering a new FDA-regulated medical product is typically one-half the time between the date a clinical investigation on human beings is begun and the submission date of an application for marketing approval of the product, plus the time between the submission date of an application for approval of the product and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the marketing approvals. The U.S. Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Data Privacy and the Protection of Personal Information

We are subject to numerous laws and regulations governing data privacy and the protection of personal information of patients, clinical investigators, employees, and vendors/business contacts, including in relation to medical records and other health information, credit card data and financial information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which will continue to affect our business. In the United States, we may be subject to state security breach notification laws, state laws protecting the privacy of health and personal information and federal and state consumer protections laws that regulate the collection, use, disclosure and transmission of personal information. These laws overlap and often conflict and each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues. If we fail to comply with applicable laws and regulations, we could be subject to penalties or sanctions, including criminal penalties as well as reputational harm. Our customers and research partners must comply with laws governing the privacy and security of health information, including HIPAA, HITECH and state health information privacy laws. If we knowingly obtain protected health information without the authority to do so, our research collaborators may be subject to enforcement, and we may have direct liability for the unlawful receipt of protected health information or for aiding and abetting a HIPAA violation.

Even when HIPAA does not apply, according to the Federal Trade Commission ("FTC"), failing to take appropriate steps to keep consumers' personal information secure, or failing to provide a level of security commensurate to promises made to individual about the security of their personal information (such as in a privacy notice), may constitute unfair or deceptive acts or practices in violation of Section 5(a) of the Federal Trade Commission Act (the "FTC Act"). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule. The FTC and states' Attorneys General have brought enforcement actions and prosecuted some data breach cases as unfair and/or deceptive acts or practices under the FTC Act and comparable state laws.

State laws protecting health and personal information are becoming increasingly stringent. For example, California has implemented the California Confidentiality of Medical Information Act that imposes restrictive requirements regulating the use and disclosure of health information and other personally identifiable information, and California has also adopted the California Consumer Privacy Act of 2018 ("CCPA"), which went into effect in January of 2020. The CCPA establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, requiring covered companies to provide new disclosures to consumers about such companies' practices for collection and use of consumer data, and providing consumers new ways to opt-out of certain sales or transfers of personal information. In addition, the CCPA creates a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. While there is an exception for protected health information that is subject to HIPAA and clinical trial regulations, as the law currently written, the CCPA may impact our business activities. More recently, a new privacy law, the California Privacy Rights Act ("CPRA") was approved by California voters. The CPRA went into effect in January of 2023, modifying and strengthening the CCPA significantly, potentially resulting in further uncertainty, additional costs and expenses in an effort to comply and additional potential for harm and liability for failure to comply. Among other things, the CPRA established a new regulatory authority, the California Privacy Protection Agency, which has the authority to promulgate new privacy regulations and enforce California privacy laws and regulations. Moreover, multiple states have enacted their own privacy laws similar to the CCPA, and other states are considering proposals for such laws. As more states implement their own privacy laws and regulations, and the interplay of federal and state laws becomes subject to varying interpretations by courts and government agencies, pharmaceutical companies

and clinical research collaborators may become exposed to complex compliance issues and the potential for additional expenses or liability.

Environmental, Health and Safety Regulation

We are subject to numerous federal, state and local environmental, health and safety (“EHS”) laws and regulations relating to, among other matters, safe working conditions, product stewardship, environmental protection, and handling or disposition of products, including those governing the generation, storage, handling, use, transportation, release, and disposal of hazardous or potentially hazardous materials, medical waste, and infectious materials that may be handled by our research laboratories. Some of these laws and regulations also require us to obtain licenses or permits to conduct our research and development operations. If we fail to comply with such laws or obtain and comply with the applicable permits, we could face substantial fines or possible revocation of our permits or limitations on our ability to conduct our operations. Certain of our development and manufacturing activities involve use of hazardous materials, and we believe we are in compliance with the applicable environmental laws, regulations, permits, and licenses. However, we cannot ensure that EHS liabilities will not develop in the future. EHS laws and regulations are complex, change frequently and have tended to become more stringent over time. We cannot predict the impact on our business of new or amended laws or regulations or any changes in the way existing and future laws and regulations are interpreted or enforced, nor can we ensure we will be able to obtain or maintain any required licenses or permits.

U.S. Foreign Corrupt Practices Act

In general, the Foreign Corrupt Practices Act of 1977, as amended, (“FCPA”) prohibits offering to pay, paying, promising to pay, or authorizing the payment of money or anything of value to a foreign official in order to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business for or with, or in order to direct business to, any person. The prohibitions apply not only to payments made to “any foreign official,” but also those made to “any foreign political party or official thereof,” to “any candidate for foreign political office” or to any person, while knowing that all or a portion of the payment will be offered, given, or promised to anyone in any of the foregoing categories. “Foreign officials” under the FCPA include officers or employees of a department, agency, or instrumentality of a foreign government. The term “instrumentality” is broad and can include state-owned or state-controlled entities.

Importantly, United States authorities that enforce the FCPA, including the DOJ, deem most healthcare professionals and other employees of foreign hospitals, clinics, research facilities and medical schools in countries with public healthcare or public education systems to be “foreign officials” under the FCPA. When we or our agents interact with foreign healthcare professionals and researchers in testing our product candidates abroad (and marketing products in the future, if any are approved), we must have policies and procedures in place sufficient to prevent us and agents acting on our behalf from providing any bribe, gift or gratuity, including excessive or lavish meals, travel or entertainment in connection securing required permits and approvals such as those needed to initiate clinical trials in foreign jurisdictions. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the maintenance of books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and the development and maintenance of an adequate system of internal accounting controls for international operations. The Securities and Exchange Commission (“SEC”) is involved with the books and records provisions of the FCPA.

Government Regulation Outside the U.S.

In addition to regulations in the United States, we may be subject to a variety of regulations in foreign jurisdictions that govern, among other things, clinical trials and any commercial sales and distribution of our products, if approved, either directly or through our distribution partners. Whether or not we obtain FDA approval for a product candidate, we must obtain the requisite approvals from regulatory authorities in foreign jurisdictions prior to the commencement of clinical trials or marketing and sale of the product in those countries. The foreign regulatory approval process includes risks that are the same as or similar to the ones described above relating to the FDA submission, review and approval processes, and the time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Some foreign jurisdictions have a drug product approval process similar to that in the United States, which requires the submission of a clinical trial application, or CTA, much like the IND prior to the commencement of clinical studies. In Europe, for example, a CTA must be submitted in accordance with the Clinical Trials Regulation and must involve an independent ethics committee, much like the FDA and a responsible IRB, respectively. Once the CTA is authorized, clinical trial development may proceed. To obtain regulatory approval of a therapeutic product candidate under European Union (“EU”) regulatory systems, we would be required to submit a marketing authorization application, which is similar to the NDA, except that there are different pathways to obtain marketing authorization, such as the centralized and decentralized procedures. For countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, and recently the United Kingdom, the requirements governing the conduct of clinical trials, product approval, pricing and reimbursement vary from country to country. Regulatory approval in

one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others. Moreover, even though certain clinical trials may support product approval in the United States, some nations may not consider such clinical studies adequate to support marketing authorization or may require that additional studies be performed on their citizens. In addition, in certain foreign markets, the pricing of drug products is subject to government control and reimbursement may in some cases be unavailable or insufficient. We face the risk that the resulting prices would be insufficient to generate an acceptable return to us or any future partner of ours. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

Regulation of Pharmaceutical Products in the European Union

As in the United States, pharmaceutical products can be marketed in the EU only if a marketing authorization from the competent regulatory agencies has been obtained. Similar to the United States, the various phases of preclinical and clinical research in the EU are subject to significant regulatory controls.

Pursuant to the European Clinical Trials Directive, a system for the approval of clinical trials in the EU had been implemented through national legislation of the member states. Under the previous system, an applicant obtained approval from the competent national authority of an EU member state in which the clinical trial was conducted. Furthermore, the applicant could only start a clinical trial after a competent ethics committee had issued a favorable opinion. In April 2014, the new Clinical Trials Regulation, (EU) No 536/2014 (“Clinical Trials Regulation”) was adopted and became effective on January 31, 2022. The Clinical Trials Regulation is directly applicable in all the EU Member States, repealing the previous Clinical Trials Directive 2001/20/EC. The extent to which ongoing clinical trials will be governed by the Clinical Trials Regulation depends on when the Clinical Trials Regulation becomes applicable and on the duration of the individual clinical trial. On January 31, 2025, the Clinical Trials Regulation became applicable to clinical trials which were initially authorized under the Clinical Trials Directive.

The Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the “EU portal” called the Clinical Trial Information System (“CTIS”); a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials. Use of the CTIS became mandatory for new clinical trial application submissions as of February 1, 2023.

To obtain marketing approval of a drug in the EU, an applicant must submit a marketing authorization application (“MAA”) either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all EU member states, Iceland, Lichtenstein and Norway. The centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products (such as gene-therapy, somatic cell-therapy or tissue-engineered medicines) and products with a new active substance indicated for the treatment of specific 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. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the European Medicines Agency (“EMA”) is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the Committee for Medicinal Products for Human Use (“CHMP”). Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is 150 days, excluding stop-clocks.

The decentralized procedure is available to applicants who wish to market a product in specific EU member states where such product has not received marketing approval in any EU member states before. The decentralized procedure provides for an applicant to apply to one-member state to assess the application (the reference member state) and specifically list other member states in which it wishes to obtain approval (concerned member states). Under this procedure, an applicant submits an application based on identical dossiers and related materials, including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference member state and each concerned member state. The reference member state prepares a draft assessment report and drafts of the related materials within 210 days after receipt of a valid application which is then reviewed and approved commented on by the concerned member states. Within 90 days of receiving the reference member state’s assessment report and related materials, each concerned member state must decide whether to approve the assessment report and related materials.

In the EU, only products for which marketing authorizations have been granted may be promoted. A marketing authorization is valid for five years in principle and the marketing authorization may be renewed after the initial five-year period on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any marketing authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause).

Moreover, even if authorized to be marketed in the EU, prescription-only medicines may only be promoted to healthcare professionals, not the general public. All promotion should be in accordance with the particulars listed in the summary of product characteristics. Promotional materials must also comply with various laws, and codes of conduct developed by pharmaceutical industry bodies in the EU which govern (among other things) the training of sales staff, promotional claims and their justification, comparative advertising, misleading advertising, endorsements, and (where permitted) advertising to the general public. Failure to comply with these requirements could lead to the imposition of penalties by the competent authorities of the EU member states. The penalties could include warnings, orders to discontinue the promotion of the drug product, seizure of promotional materials, fines and possible imprisonment.

In April 2023 the European Commission issued a proposal for a new Directive and a new Regulation to revise and replace the existing general pharmaceutical legislation. As of December 2025, the three EU institutions, the European Commission, the European Parliament and the Council of the EU are in the process of negotiating the final content of the new Directive and Regulation. Once negotiations are complete, the European Parliament and the Council of the EU will vote on whether to approve the Directive and Regulation. If adopted and implemented as currently proposed, these revisions will significantly change several aspects of drug development and approval in the EU.

Regulation of Pharmaceutical Products in the United Kingdom

As of January 1, 2021, European Union law no longer directly applies in the United Kingdom. The United Kingdom has adopted existing European Union medicines regulation as standalone United Kingdom legislation with some amendments to reflect procedural and other requirements with respect to marketing authorizations and other regulatory provisions.

The Medicines and Healthcare products Regulatory Agency, or MHRA, is responsible for regulating the United Kingdom medicinal products market (Great Britain and Northern Ireland). An MHRA authorization must be obtained for each medicine to be marketed in the regions that comprise the United Kingdom. On January 1, 2021, all European Union marketing authorizations were converted to United Kingdom marketing authorizations subject to a manufacturer opt-out. The United Kingdom has introduced separate, specific processes for regulatory submissions and medicinal product marketing authorization, and MHRA guidance states that the United Kingdom will have the power to take into account marketing authorizations made under the European Union decentralized and mutual recognition procedures. On January 1, 2024, the MHRA launched the International Recognition Procedure, or IRP, which provides for an expedited authorization procedure for products that have received positive marketing authorization decisions from trusted partner agencies, such as the EMA or the FDA. There are two available routes for assessment and recognition under the IRP:

- Recognition Route A – 60 days from validation of submission
 - Application must be based on a Reference Regulator, or RR, marketing authorization within the previous two years
 - Any significant differences from the quality dossier approved by the RR marketing authorization requires assessment under Recognition Route B
 - Evidence of cGMP compliance for manufacturing sites should be provided with submission
 - None of the Recognition Route B criteria are met
- Recognition Route B – 110 days from validation of submission with one planned clock stop (up to 60 days) at day 70 to allow applicant to respond to issues identified during review
 - Application must be based on a RR marketing authorization within the previous 10 years
 - Criteria requiring Recognition Route B include, among other things:
 - The RR marketing authorization granted a conditional or exceptional circumstances marketing authorization

- Additional manufacturing sites included in the application were not assessed by the RR marketing authorization or a manufacturing site is not cGMP certified
- There are substantial changes to the manufacturing process compared to the process approved by the RR marketing authorization
- Certain product types (e.g., advanced therapy medicinal products, orphan medicines, over-the-counter medicines)
- A risk management plan was not assessed under the RR marketing authorization
- The RR marketing authorization required one or more post-authorization safety studies for the product
- A companion diagnostic is necessary for correct use of the product and the diagnostic test is not authorized in the EU or UK

United Kingdom medicines legislation is subject to future regulatory change under the Medicines and Medical Devices Act 2021. This act sets out a framework for the adoption of medicines regulation.

Different rules apply in Northern Ireland following implementation of the Northern Ireland Protocol, under which European Union central marketing applications continue to apply there. However, in March 2023, the United Kingdom government and the European Commission reached agreement on a regulatory framework to replace the Northern Ireland Protocol, referred to as the Windsor Framework. The Windsor Framework is effective as of January 1, 2025, and requires changes to the system that was previously in effect under the Northern Ireland Protocol, including the regulation of pharmaceutical products in the United Kingdom. Specifically, the MHRA will be responsible for approving all medicines intended to be marketed in the United Kingdom (including Northern Ireland), while the EMA will no longer be involved in approving medicines intended for sale in Northern Ireland.

The Trade and Cooperation Agreement, which sets forth a framework for partnership between the European Union and the United Kingdom, became effective as of January 1, 2021. The Trade and Cooperation Agreement between the European Union and the United Kingdom contains an Annex in relation to medicinal products with the objective of facilitating availability of medicines, promotion of public health and consumer protection in respect of medicinal products. The Annex provides for mutual recognition of cGMP inspections and certificates, meaning that manufacturing facilities do not need to undergo duplicate inspections for the two markets. The Annex establishes a Working Group on Medicinal Products to deal with matters under the Trade and Cooperation Agreement, facilitate co-operation and for the carrying out of technical discussions. It is expected that further bilateral discussions will continue with respect to regulatory areas not the subject of the Trade and Cooperation Agreement, including pharmacovigilance. The Trade and Cooperation Agreement also does not include reciprocal arrangements for the recognition of batch testing certification. However, the United Kingdom has listed approved countries, including the EEA which will enable United Kingdom importers and wholesales to recognize certain certification and regulatory standards. The European Commission has not adopted such recognition procedures.

It is expected that the establishment of a separate United Kingdom authorization system, albeit with transitional recognition procedures in the United Kingdom, will lead to additional regulatory costs. In addition, additional regulatory costs may be incurred with respect to the lack of mutual recognition of batch testing and related regulatory measures.

Human Capital Resources

As of December 31, 2025, we had 21 full-time employees. Senior management and professional employees have had prior experience in pharmaceutical and/or biotechnology companies. None of our employees are covered by collective bargaining agreements. We believe that our relations with our employees are good. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees, advisors and consultants. The principal purposes of our equity incentive plans are to attract, retain and reward personnel through the granting of equity-based compensation awards in order to emphasize increasing stockholder value and our success by motivating such individuals to perform to the best of their abilities and achieve our objectives.

We recognize that our industry is specialized and dynamic, and a significant aspect of our success is our continued ability to execute our human capital strategy of attracting, engaging, developing and retaining highly skilled talent. There is fierce competition both within our industry and in the geographic locations in which we operate for highly skilled talent, and we offer a robust set of benefits, career-enhancing learning experiences and initiatives aligned with our mission, vision, and values in order to attract qualified prospective employees and to retain and motivate our employees. We offer competitive compensation based on industry benchmarking provided by our independent compensation consultant to the Compensation Committee of the Board of Directors for our employees and strongly embrace a pay for performance philosophy in setting and adjusting compensation.

Our Code of Business Conduct and Ethics clearly outlines our commitment to diversity and inclusion, where all employees are welcomed in an environment designed to make them feel comfortable, respected, and accepted regardless of their age, race, national origin, gender, religion, disability or sexual orientation. We have a set of policies explicitly setting forth our expectations for nondiscrimination and a harassment-free work environment. We are also a proud equal opportunity employer and cultivate a highly collaborative and entrepreneurial culture.

Summary of Risk Factors

Our business, financial condition, operating results and cash flows are subject to numerous risks and uncertainties that are summarized below. The summary of risk factors below should be read together with the more detailed discussion of risks set forth following this section under the heading “Risk Factors,” as well as elsewhere in this Annual Report.

- The proposed acquisition by Kuva is subject to a number of conditions beyond our control. Failure to complete the proposed acquisition within the expected time frame, or at all, could have a material adverse effect on our business, operating results, financial condition and our stock price.
- We have incurred substantial losses and negative cash flow from operations in the past and expect to continue to incur losses and negative cash flow for the foreseeable future. Additionally, we anticipate that we will need substantial additional financing to continue our operations; if we are unable to raise additional capital, we may be forced to delay, reduce or eliminate some or all of our product development programs, and our business will consequently be materially harmed.
- There is substantial doubt regarding our ability to continue as a going concern.
- We are substantially dependent on our investigational product candidate, certepetide. If we are unable to advance certepetide or any of our other product candidates through clinical development, obtain regulatory approval and ultimately begin commercializing, or experience significant delays in doing so, our business will be materially harmed.
- The commercial potential and profitability of our product candidates are unknown. We currently have no marketing and sales organization and have no experience in marketing products, and our products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community.
- We may not be able to file INDs or IND amendments to commence additional clinical trials on the timelines we expect, and even if we are able to, the regulators may not permit us to proceed.
- Results from a clinical trial, once completed, may be less clear than expected, which may hinder our efforts to obtain regulatory approval for our product candidates.
- We may be unable to manage multiple late-stage clinical trials for a variety of product candidates simultaneously.
- Product candidates that appear promising in research and development may be delayed or may fail to reach later stages of clinical development.
- If serious or unacceptable side effects are identified during the development of any of our product candidates, we may need to abandon or limit our development of that product candidate.
- A Fast Track or breakthrough therapy designation by the FDA (or other regulatory authorities) and other similar regulatory designations may not lead to a faster development, regulatory review, or approval process.
- Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates, which failure would prevent or delay acquisition of requisite capital to complete development and/or regulatory approval and commercialization.
- We presently rely on contract manufacturing organizations to produce our product candidates at development and commercial scale quantities and have not yet qualified an alternate manufacturing supply, which could negatively impact our ability to meet any future demand for the products.
- We currently rely heavily on contract research organizations to conduct our studies. Their inability to recruit or operationalize our study could negatively impact our ability to meet our milestone timelines.
- Any supply chain disruption could impact our ability to perform clinical trials and seek future regulatory submissions.
- We may enter into collaborations, strategic alliances, additional licensing arrangements, acquisitions, business combinations and/or other strategic transactions, and we may not realize the benefits of any such arrangement.

- If competitors develop and market products that are more effective, safer, or less expensive than our product candidates or offer other advantages, our commercial prospects will be limited.
- We may need to grow the size or change the composition of our organization and may experience difficulties in managing this growth or change.
- We may be subject to significant product liability claims and litigation, including potential exposure from the use of our product candidates in human subjects, and our insurance may ultimately be inadequate to cover claims that may arise.
- We may be unable to hire or retain key officers or employees needed to implement our business strategy.
- A variety of risks associated with operating our business internationally could materially adversely affect our business.
- We conduct operations through our Australian subsidiary. If we lose our ability to operate in Australia, or if the subsidiary loses eligibility for certain Australian tax credits, our business and results of operations could suffer.
- Our internal computer systems, or those used by our clinical investigators, clinical research organizations or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of development programs for our product candidates.
- The development and commercialization of our product candidates are subject to extensive regulation and the failure to receive regulatory approvals would have a material and adverse effect on our business and prospects. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that it will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.
- We may be subject to numerous and varied privacy and security laws, and our failure to comply could result in penalties and reputational damage.
- We will continue to be subject to extensive regulation following any product approvals, and if we fail to comply with these regulations, we may suffer a significant setback in our business.
- Healthcare companies have been the subject of federal and state investigations, and we could become subject to investigations in the future.
- It is uncertain to what extent government, private health insurers and third-party payors will approve coverage or provide reimbursement for the therapies and products to which our research and development relate. Legislation and regulatory proposals intended to contain healthcare costs may adversely affect our business.
- Inadequate funding for the FDA, the SEC and other government agencies in the U.S. or elsewhere, and/or large staff turnovers at these agencies could hinder 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.
- If we are unable to obtain or maintain our licenses, patents or other intellectual property we could lose important protections that are material to continuing our operations and our future prospects.
- Litigation and third-party claims relating to intellectual property are expensive, time-consuming and uncertain, and we may be unsuccessful in our efforts to protect against infringement by third parties or defend ourselves against claims of infringement.
- Our ability to utilize our net operating loss carryforwards and tax credit carryforwards may be subject to limitations.
- Our stock price has been, and will likely continue to be, highly volatile and accurately predicting positive or negative movement relative to our results and announcements historically has been elusive.
- We may fail to comply with the continued listing requirements of the Nasdaq Capital Market, such that our common stock may be delisted and our ability to access the capital markets could be negatively and materially impacted.
- Future fundraising and strategic transactions may cause dilution, and we currently have securities outstanding that are exercisable for our common stock, which could result in significant additional dilution.
- Provisions in our amended and restated certificate of incorporation and by-laws and Delaware law may inhibit a takeover, which could limit the price investors are willing to pay for our common stock and could entrench management.

- Failure to maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business and stock price.

ITEM 1A. RISK FACTORS.

Our business, financial condition, operating results and cash flows can be affected by a number of factors, including, but not limited to, those set forth below, any one of which could cause our actual results to vary materially from recent results or from our anticipated future results. The risks described below are not the only ones we face, but those we currently consider to be material. There may be other risks which we now consider immaterial, or which are unknown or unpredictable, with respect to our business, our competition, the regulatory environment or otherwise that could have a material adverse effect on our business, financial condition and results of operations.

RISKS RELATED TO THE PROPOSED ACQUISITION BY KUVA

The proposed acquisition by Kuva is subject to a number of conditions beyond our control. Failure to complete the proposed acquisition within the expected time frame, or at all, could have a material adverse effect on our business, operating results, financial condition and our stock price.

On March 6, 2026, we entered into the Merger Agreement, pursuant to which, and upon the terms and subject to the conditions thereof, Purchaser will commence a tender offer to purchase all of our issued and outstanding shares of common stock in exchange for (i) \$5.00 per share, net to the seller in cash, without interest, but subject to any applicable withholding of taxes plus (ii) one non-tradeable CVR, which represents the contractual right to receive a contingent cash payment of \$1.00 per CVR if the Milestone is met as further described in the CVR Agreement. If certain conditions are satisfied and the Offer is consummated, Kuva would acquire any remaining shares for the Offer Price by a merger of Purchaser with and into us.. Following completion of the transaction, we will become part of Kuva, a privately-held company, and our common stock will be delisted from Nasdaq. We will also apply to deregister our common stock and cease to be a reporting company under the United States Securities Exchange Act of 1934, as amended. Under the Merger Agreement, the Offer and the Merger will be subject to customary closing conditions for a transaction of this nature. Kuva will be required to close on the Offer so long as there shall be validly tendered a number of Shares that represents (and will represent immediately following the consummation of the Offer) at least a majority of the aggregate voting power of all Shares then outstanding.

We cannot predict whether and when the conditions to closing will be satisfied. Until these conditions are satisfied and we and Kuva complete the proposed transaction, our business, operating results and financial condition are exposed to certain risks due to the effect of the pending proposed transaction, including:

- the possibility of disruption to our business and operations, including diversion of management attention and resources;
- the inability to attract and retain key personnel, and the possibility that our current employees could be distracted, and their productivity decline as a result;
- the inability to pursue alternative business opportunities or make changes to our business pending the completion of the proposed transaction, and other restrictions on our ability to conduct our business;
- the amount of the costs, fees, expenses, and charges related to the proposed transaction;
- our inability to solicit other acquisition proposals; and
- the market price of our common stock could decrease if the proposed transaction is not completed or if there exists a market perception that the transaction will not be completed.

If the proposed transaction does not close, we would be exposed to additional risks, including:

- to the extent the current market price of our common stock reflects an assumption that the proposed transaction will be completed, the price of our common stock could decrease if the proposed transaction is not completed;
- investor confidence could decline, shareholder litigation could be brought against us, relationships with service providers, investors, and other business partners may be adversely impacted, we may be unable to retain key personnel, and our financial condition may be adversely impacted due to costs incurred in connection with the pending transaction; and
- the requirement that we pay a termination fee of \$2,000,000 if the Merger Agreement is terminated in certain circumstances, including if we terminate to accept and enter into an agreement with respect to a superior proposal.

RISKS RELATED TO OUR FINANCIAL CONDITION AND CAPITAL REQUIREMENTS

We have incurred substantial losses and negative cash flow from operations in the past and expect to continue to incur losses and negative cash flow for the foreseeable future.

We have a limited operating history as Lisata Therapeutics, Inc, limited capital, and limited sources of revenue. Since our inception in 1980 through December 31, 2025, we have incurred aggregate net losses of approximately \$564.7 million. Our net losses from continuing operations attributable to common stockholders for the years ended December 31, 2025 and December 31, 2024 were approximately \$16.6 million and \$20.0 million, respectively. As of December 31, 2025, our cash and cash equivalents and marketable securities were \$16.0 million. Our current business has not generated revenues in the past and for the foreseeable future we do not expect it to generate revenue to be sufficient to cover costs attributable to that business or to our operations as a whole, including our development activities associated with our product candidates. Ultimately, we may never generate sufficient revenue from our business to reach profitability, generate positive cash flow or sustain, on an ongoing basis, our current or projected levels of product development and other operations.

We anticipate that we will need substantial additional financing to continue our operations; if we are unable to raise additional capital, we may be forced to delay, reduce or eliminate some or all of our product development programs, and our business will be materially harmed.

Our current operating plan will require significant levels of additional capital to fund the continued development of our product candidates and our clinical development activities. Based on our current expected capital needs, we believe that our projected capital will fund our current proposed operations into early 2027, encompassing anticipated data milestones from all of our ongoing clinical trials.

Our clinical activities may be expected to continue to increase in size, complexity and geographic reach as our programs are advanced and they will require significant investment over a period of several years before they yield results that could potentially be approved by health authorities and commercialized by us or a partner, if ever. Even if data from our current Phase 2 clinical trials for our product candidates were deemed positive, we most likely would be required to conduct additional clinical trials of the product candidates, including larger and more expensive pivotal Phase 3 trials, to pursue commercialization of the candidates. To do so, we will need to raise substantial additional capital, enter into collaboration agreements with third parties or undertake any combination thereof. If we are unsuccessful in our efforts to raise capital or find collaborative partners, we will likely need to otherwise delay or abandon the trials.

The amount and timing of our future capital requirements also will likely depend on many other factors, including but not limited to:

- the scope, progress, results, costs, timing and outcomes of our research and development programs and product candidates;
- our ability to control timing of results availability as well as the timing and content of related public announcements based on existing contracts with collaborators, particularly if those contracts were inherited as part of a business transaction;
- our ability to enter into any collaboration agreements with third parties for our product candidates and the timing and terms of any such agreements;
- the costs associated with the consummation of one or more strategic transactions;
- the timing of, and the costs involved in obtaining, regulatory approvals for our product candidates, a process which could be particularly lengthy;
- the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities relating thereto;
- the cost of expansion of our development operations and personnel; and
- the availability of, or our access to, state or federal government awards.

To both fund our clinical trials and support our future operations, it is highly probable that we would require raising capital through a variety of different public and/or private financings vehicles. This could include, but not be limited to, utilization of our at-the-market offering agreement with H.C. Wainwright & Co., LLC, potential issuances of other debt or equity securities in public or private financings and/or sale or licensing of assets. If we raise capital through the sale of equity, or securities convertible into equity, it would likely result in dilution to our then-existing stockholders. Servicing the interest and principal repayment obligations under debt we incur, or whether any such debt is called, would divert funds that might otherwise be

available to support research and development, clinical or commercialization activities. In addition, debt financing involves covenants that restrict our ability to operate our business. In certain cases, we also may seek funding through collaborative arrangements that would likely require us to relinquish certain rights to our technology or product candidates and diminish our share in the future revenues associated with the partnered product.

Ultimately, we may be unable to raise capital or enter into collaborative relationships on terms that are acceptable to us, if at all. Our inability to obtain the necessary capital or financing to fund our future operating needs would materially adversely affect our business, results of operations and financial condition.

There is substantial doubt regarding our ability to continue as a going concern.

There is substantial doubt regarding our ability to continue as a going concern. Our continued operations are dependent upon our ability to obtain additional capital. As of December 31, 2025, our cash and cash equivalents were \$16.0 million. Our management believes that such cash and cash equivalents will not be sufficient to fund our operating expenses and capital requirements for twelve months after the date that the financial statements included in this Annual Report are issued. We will require significant additional funding to advance any of our product candidates beyond the short term. Our ability to continue as a going concern will depend on our ability to obtain additional funding, as to which no assurances can be given. Our lack of sufficient liquidity could make it more difficult for us to secure additional financing or enter into strategic relationships on terms acceptable to us, if at all, and may materially and adversely affect the terms of any financing that we may obtain and our public stock price generally. We continue to analyze various alternatives, including debt or equity financings or other arrangements.

We have never generated any revenue from product sales and our ability to generate revenue from product sales and become profitable depends significantly on our success in a number of factors.

We have no products approved for commercial sale, have not generated any revenue from product sales, and do not anticipate generating any revenue from product sales until sometime after we have received regulatory approval for the commercial sale of a product candidate, which may never occur. Our ability to generate revenue from product sales and achieve profitability depends significantly on our success in many factors, including:

- completing research regarding, and non-clinical and clinical development of, our current and future product candidates;
- obtaining regulatory approvals and marketing authorizations for product candidates for which we complete clinical trials;
- developing a sustainable, scalable and economically feasible manufacturing process for our product candidates;
- identifying and contracting with contract manufacturers that have the ability and capacity to manufacture our development products and make them reliably at an acceptable cost;
- launching and commercializing product candidates for which we obtain regulatory approvals and marketing authorizations, either directly or with a collaborator or distributor;
- obtaining market acceptance of our product candidates as viable treatment options;
- ensuring ongoing regulatory compliance post-approval and with respect to sales and marketing of future products;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and/or developing new product candidates;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and
- attracting, hiring, and retaining qualified personnel.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by regulatory agencies, domestic or foreign, to change our manufacturing processes or assays, or to perform clinical, non-clinical, or other types of studies in addition to those that we currently anticipate. If we are successful in obtaining regulatory approvals to market one or more of our product candidates, our revenue will depend, in part, upon the size of the markets in the territories for which we obtain regulatory approval, the accepted price for the product, the ability to

receive reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable disease patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate sufficient revenue from the sale of any approved products, we may never become profitable.

If our status as a smaller reporting company changes, Section 404(b) of the Sarbanes-Oxley Act of 2002 may require an independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Any delays or difficulty in satisfying these requirements could adversely affect our future results of operations and our stock price.

Section 404(b) of the Sarbanes-Oxley Act of 2002 requires an independent registered public accounting firm to test the internal control over financial reporting of public companies, and to report on the effectiveness of such controls. Under the Dodd Frank Wall Street Reform and Consumer Protection Act of 2010, we are exempt from Section 404(b) as long as we remain a smaller reporting company or a non-accelerated filer. If our status as a smaller reporting company changes, we may be required to comply with this auditor attestation requirement.

In addition, we may in the future discover areas of our internal controls that need improvement, particularly with respect to businesses that we may acquire. If so, we cannot be certain that any remedial measure we take will ensure that we have adequate internal controls over our financial processes and reporting in the future. Any failure to implement the required new or improved controls, or difficulties encountered in their implementation could harm our operating results or cause us to fail to meet our reporting obligations. If we are unable to conclude that we have effective internal controls over financial reporting, or if it becomes necessary for our independent registered public accounting firm to provide us with an unqualified report regarding the effectiveness of our internal control over financial reporting and it is unable to do so, investors could lose confidence in the reliability of our financial statements. This could result in a decrease in the value of our common stock.

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

Our ability to use our federal and state net operating losses (“NOLs”) to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOLs.

Under Section 382 and Section 383 of the Code and corresponding provisions of state law, if a corporation undergoes an “ownership change,” its ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. A Section 382 “ownership change” is generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period. Even if we achieve profitability, we may not be able to utilize a material portion of our NOL carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

RISKS RELATED TO OUR PRODUCT DEVELOPMENT EFFORTS

We are substantially dependent on our investigational product candidate, certepetide. If we are unable to advance certepetide or any of our future product candidates through clinical development, obtain regulatory approval and ultimately commercialize certepetide or any of our other product candidates, or experience significant delays in doing so, our business will be materially harmed.

Our investigational product candidate certepetide is still in clinical development. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful clinical development and eventual commercialization of certepetide and potentially one or more of our other product candidates. The success of our product candidates will depend on many factors, including the following:

- successful completion of preclinical and clinical studies;
- clearance of INDs, comparable foreign clinical trial applications (“CTAs”) and clinical protocols for our planned clinical trials or future clinical trials;
- Regulator acceptance of our development strategy and resultant clinical data;
- successful initiation of clinical trials;

- successful patient enrollment in and completion of clinical trials;
- safety, tolerability and efficacy profiles for our product candidates that are satisfactory to regulators for marketing approval;
- receipt of marketing approvals for our product candidates from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates, if any product candidates are approved;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining third-party coverage and adequate reimbursement;
- maintaining a continued acceptable safety profile of our products following approval; and
- factors we may not be able to control, such as potential pandemics that may limit patients, principal investigators or staff or clinical site availability (e.g. the COVID-19 pandemic).

There is no guarantee that the results obtained in our current clinical studies will be sufficient to obtain regulatory approval or marketing authorization for any of our product candidates. Negative results in the development of our investigational product candidate, certepetide, in any one indication may also impact our ability to obtain regulatory approval of certepetide in other indications, either at all or within anticipated timeframes because, even though the indications are different, the underlying technology platform, manufacturing process and development process are the same. Accordingly, a failure or major issue associated with any one indication may affect the ability to obtain regulatory approval to continue or conduct clinical programs and/or obtain regulatory approval for another indication. Furthermore, although we believe based on available preclinical and clinical results that a combination of certepetide with certain anti-cancer therapeutics is more effective than the use of those therapeutics alone, this may not prove true in clinical testing of certepetide for all or any of the types of cancer. Anti-tumor activity may prove different in each of the different tumor types and/or with each of the anti-cancer therapeutic combinations we plan on evaluating. Therefore, the tumor response to certepetide plus the corresponding anti-cancer therapeutic(s) combination may be less robust in patients with some cancers compared to others. This may result in discontinuation of development of certepetide for certain tumor types and/or certain anti-cancer therapeutic(s) combinations due to insufficient clinical benefit.

In addition, because we have limited financial and personnel resources and are placing significant focus on the development of our investigational product candidate, we may forego or delay pursuit of opportunities with other future product candidates that later prove to have greater commercial potential. 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 other future product candidates for specific indications may not yield any commercially viable future product candidates. If we do not accurately evaluate the commercial potential or target market for a particular future product candidate, we may relinquish valuable rights to those future product candidates 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 future product candidates.

Our future success may be dependent on the timely and successful continued development and commercialization of our product candidates and if we encounter delays or difficulties in the development of these product candidates, our business prospects could be materially harmed.

We are dependent upon the successful development, approval and commercialization of our product candidates. Before we are able to seek regulatory approval of our product candidates, we must conduct and complete extensive clinical trials to demonstrate their safety and efficacy in humans. We have never taken a product through the regulatory approval process or successfully to U.S. or international commercialization.

Clinical testing is expensive, challenging and complex to design and execute and can take many years to complete. Importantly, a failure of one or more clinical trials can occur at any stage of testing. We may experience numerous unforeseen

events during, or as a result of clinical trials that could delay or prevent our ability to complete our clinical trials, receive regulatory approval or commercialize our product candidates, including the following:

- suspensions, delays or changes in the design, initiation, enrollment, execution or completion of required clinical trials;
- adverse changes in our financial position or significant and unexpected increases in the cost of our development programs;
- changes or uncertainties in, or additions to, the regulatory approval process that require us to alter our current development strategy;
- clinical trial results that are negative or inconclusive as to safety and/or efficacy, which would result in the need for additional clinical trials or the termination of the product's development;
- delays in our ability to manufacture our product candidates in quantities, in a form and/or at a cost that is suitable for any required clinical trials;
- intellectual property constraints that prevent us from making, using, or commercializing any of our product candidates;
- the supply or quality of our product candidates or other materials or equipment necessary to conduct clinical trials of these product candidates may be no longer available for purchase, insufficient or inadequate;
- inability to generate sufficient non-clinical, toxicology, or other in vivo or in vitro data to support the initiation and/or continuation of clinical trials;
- delays in reaching agreement on acceptable terms with prospective contract research organizations (“CROs”), contract manufacturing organizations (“CMOs”), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, CMOs and clinical trial sites;
- delays in obtaining required institutional review board approval at each clinical trial site;
- inability to submit or obtain clearance for an IND or CTA with the applicable regulators for our development candidates;
- imposition of a temporary or permanent clinical hold by the FDA or similar restrictions by other regulatory agencies for a number of reasons, including after review of an IND or protocol amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our manufacturing sites, clinical trial operations (including those of any CRO involved) or clinical trial sites; developments on trials conducted by competitors or approved products post-market for related technology that raise FDA concerns about risk to patients of the technology broadly; or if the FDA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- difficulty collaborating with patient groups, individual investigators and/or associated institutions;
- failure by our CROs, CMOs, other third parties, or us to adhere to clinical trial requirements and international regulatory standards;
- failure to perform in accordance with the FDA or international GCP requirements;
- failure to reach agreement with the FDA on a satisfactory development path of our development candidates;
- failure to resolve contradictory guidance issued by the FDA, EMA or other international regulatory bodies of relevance to our development program(s);
- delays in having patients qualify for or complete participation in a trial or return for post-treatment follow-up;
- patients dropping out of a clinical trial;
- occurrence of adverse events associated with the product candidate;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials or abandoning existing trials;
- transfer of manufacturing processes from one manufacturer and/or manufacturing site to another, operated by either a CMO or us, and delays or failure by our CMOs or us to qualify the transferred process and/or site;

- delays in and/or the inability to complete manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing; and
- the FDA may not accept clinical data from trials that are conducted in countries where the standard of care or the nature of the disease is potentially different from the United States or for other reasons.

Any inability to successfully complete non-clinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to, or we may elect to, conduct bridging studies to demonstrate the equivalence of our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market earlier than expected, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Even if we are able to successfully complete our clinical development programs for our product candidates and receive regulatory approval to market one or more of the products, if the commercial opportunities are smaller than we anticipate, our future revenues will be adversely affected, and our business may suffer.

If the size of the commercial opportunities in any of our target indications is smaller than we anticipate, or if the FDA grants our candidates approval to treat only specific subpopulations or otherwise approves the products for more narrow indications of use than we are seeking, we may not be able to achieve profitability and growth.

Even if we are able to successfully complete our clinical development program for our product candidates, and ultimately receive regulatory approval to market one or more of the products, we may, among other things:

- obtain approval for indications that are not as broad as the indications we sought;
- have the product removed from the market after obtaining marketing approval;
- encounter problems with respect to the manufacturing and/or distribution of commercial supplies;
- be subject to additional post-marketing testing requirements; and/or
- be subject to restrictions on how the product is distributed or used.

We may experience delays in enrolling patients in our clinical trials, which would delay or prevent the receipt of necessary regulatory approvals.

We may not be able to initiate or complete as planned any clinical trials if we are unable to identify and enroll a sufficient number of eligible patients to participate in the clinical trials required by the FDA or other regulatory authorities. Some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Enrollment challenges in clinical trials often result in increased development costs for a product candidate, significant delays and potentially the abandonment of the clinical trial and/or product candidate. We also may be unable to engage a sufficient number of clinical trial sites to conduct our trials. Moreover, our ability to conduct trials outside of the United States may be constrained by our inability to transport research materials to or from foreign destinations or find another source of supply.

Because our clinical trials for certepetide are focused on patients with specific solid tumors, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. For example, we cannot be certain how many patients with the cancers that certepetide is designed to target will choose to enroll in our clinical trials and/or if that number will ultimately suffice for regulatory approval.

Patient enrollment in general is affected by many factors, including:

- patient, physician and/or treating institution financial considerations;
- size of the target patient population;
- severity of the disease or disorder under investigation;
- eligibility criteria for the clinical trial in question;
- competing clinical trials involving patients diagnosed with the disease or disorder under investigation;

- perceived risks and benefits of the product candidate under study;
- approval and availability of other therapies to treat the disease or disorder that is being investigated in the clinical trial;
- willingness or unwillingness to participate in a placebo controlled clinical trial;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

In addition, the U.S. Congress amended the FDCA in 2022 to require sponsors of a Phase 3 clinical trial, or other “pivotal study” of a new drug or biologic to support marketing authorization, to design and submit a diversity action plan for such clinical trial. The action plan must describe appropriate diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. Although none of our investigational product candidates has reached Phase 3 of clinical development, we or our partners must submit a diversity action plan to the FDA by the time a Phase 3 trial, or pivotal study, protocol is submitted to the agency for review, unless we or our partners are able to obtain a waiver for some or all of the requirements for a diversity action plan. Initiation of such trials may be delayed if the FDA objects to a proposed diversity action plans for any future Phase 3 trial of our product candidates, and we or our partners may experience difficulties recruiting a diverse population of patients in attempting to fulfill the requirements of any approved diversity action plan.

Our inability to enroll a sufficient number of patients in any of our planned clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

We may not be able to file INDs or IND amendments to commence additional clinical trials on the timelines we expect, and even if we are able to, the regulators may not permit us to proceed.

We submitted an IND for certepetide on April 14, 2021, and the IND was cleared by the FDA on May 14, 2021. Still, we may not be able to file INDs, or comparable foreign CTAs in other countries or jurisdictions, for our other product candidates on the timelines we expect. For example, we may experience manufacturing delays or other delays with IND-enabling studies. Moreover, we cannot be sure that acceptance of an initial IND will result in the FDA allowing further clinical trials to begin, or that, once begun, issues will not arise that lead to the suspension or termination of clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to file INDs on the timelines we expect or to obtain regulatory authorizations for our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all.

Results from a clinical trial, once completed, may be less clear than expected, which may hinder our efforts to obtain regulatory approval for our product candidates.

Clinical trials by their nature evaluate the safety and effectiveness of an investigational product in a relatively small sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the drug candidate. If our product candidates receive marketing approval and we or others identify undesirable side effects caused by such product candidates (or any other similar drugs) after such approval, a number of potentially significant negative consequences could result, including those listed below:

- regulatory authorities may require the addition of labeling statements, such as a “boxed” warning or a contraindication;
- we may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates;
- FDA may require a Risk Evaluation and Mitigation Strategy (“REMS”) to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove affected product candidates from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and

- our reputation may suffer.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of, affect our ability to successfully commercialize, and substantially increase the costs of commercializing, the affected products, if approved, and could significantly impact our ability to generate revenues.

We and our partners are conducting clinical trials for product candidates in many countries outside of the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials where the preponderance of data are generated in a foreign jurisdiction.

We have in the past conducted clinical trials in Australia and Japan, and we may in the future choose to conduct one or more clinical trials outside the United States, including in Canada, Australia, Europe and/or Asia. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority, respectively, may be subject to certain conditions or may not be accepted at all. For example, in cases where data from foreign clinical trials are intended to support marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign clinical trial data alone unless (i) the data are agreed by FDA to be applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP requirements; and (iii) the data may be considered valid without the need for an on-site inspection or, if the FDA considers an inspection necessary, the agency is able to validate the data through an on-site inspection or other means. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in product candidates that we develop not receiving approval for commercialization in the applicable jurisdiction.

We may be unable to manage multiple late-stage clinical trials for a variety of product candidates simultaneously.

As our current clinical trials progress, we may need to manage multiple late-stage clinical trials simultaneously in order to continue developing all of our current product candidates. Typically, early-stage trials involve relatively small numbers of patients in relatively few clinical sites. Late-stage (e.g., Phase 3) trials may involve very large numbers of patients in a larger number of sites and may require facilities in several countries. Therefore, the project management required to supervise and control such an extensive program is substantially larger than for early-stage programs. As the need for these resources is not known until some months before the trials begin, it is necessary to recruit large numbers of experienced and talented individuals very quickly. If the labor market does not allow this team to be recruited quickly, the sponsor is faced with a decision to delay the program or to initiate it with inadequate management resources. This may result in recruitment of inappropriate patients, inadequate monitoring of clinical investigators and inappropriate handling of data or data analysis. Consequently, it is possible that conclusions of efficacy or safety may not be acceptable to permit submission of an NDA for any one of the above reasons or a combination of several. Additionally, any such failure may result in regulatory liability for the sponsor, negative publicity, and other adverse impacts on the business or its operations.

Any disruption to our access to the reagents, devices, materials or equipment we are using in the clinical development of our product candidates would adversely affect our ability to perform clinical trials and seek future regulatory submissions.

Reagents, devices, materials and systems that we are using in our clinical trials, that we intend to use in our planned clinical trials and that we may need or use in future commercial production, are provided by unaffiliated third parties. Any lack of continued availability of these reagents, devices, materials and systems for any reason would have a material adverse effect on our ability to complete these studies and could adversely impact our ability to achieve commercial manufacture of our planned therapeutic products. Although other available sources for these reagents, devices, materials and systems may exist in the marketplace, we have not evaluated their cost, effectiveness, or intellectual property foundation and therefore cannot guarantee the suitability or availability of such other potential sources.

The initiation of pivotal Phase 3 clinical trials for our product candidates requires the validation and establishment of manufacturing controls that may delay product development timelines.

To conduct pivotal Phase 3 clinical trials, we are required to have certain validated and established manufacturing controls with respect to the identity, strength, quality and purity of our product candidates when administered to patients. If we determine that the results of any Phase 2 clinical trial we may conduct support Phase 3 development, we expect to initiate and complete one or more pivotal Phase 3 clinical trials for such programs and would need to address any outstanding chemistry, manufacturing and controls (“CMC”) requirements of the FDA or other relevant regulatory authority prior to initiating such trials. We may not be successful in our efforts to address any CMC issues raised by the FDA or other relevant regulatory authority. If we cannot initiate, or if we are delayed in initiating, a pivotal Phase 3 clinical program as a result of our failure to satisfy regulatory CMC concerns, the timing of completing, developing and making a regulatory submission for

commercialization of our product candidates would be delayed, or we may be unable to seek regulatory approval to commercialize our products at all.

Product candidates that appear promising in research and development may be delayed or may fail to reach later stages of clinical development.

The successful development of pharmaceutical product candidates is highly uncertain. Product candidates that appear promising in research and development and early clinical trials may be delayed or fail to reach later stages of development. Decisions regarding the further development of product candidates must be made with limited and incomplete data, which makes it difficult to ensure or even accurately predict whether the allocation of limited resources and the expenditure of additional capital on specific product candidates will result in desired outcomes. Non-clinical and clinical data can be interpreted in different ways, and negative or inconclusive results or adverse events during a clinical trial could delay, limit or prevent the development of a product candidate.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Exploratory trends and results observed in earlier stage clinical trials, particularly trends and results observed for small subsets that were not pre-specified, may not be replicated in later stage clinical trials. Product candidates in Phase 3 clinical trials may fail to demonstrate sufficient efficacy despite having progressed through initial clinical trials, even if certain exploratory subset analyses of primary or secondary endpoints in those early trials showed trends toward efficacy or, in some analyses, nominal statistical significance. The results of clinical trials in one set of patients or line of treatment may not be predictive of those obtained in another.

If serious or unacceptable side effects are identified during the development of any of our product candidates, we may need to abandon or limit our development of that product candidate.

All of our product candidates are in clinical development, and their risk of failure is high. It is impossible to predict when or if any of our product candidates will prove effective and safe in humans or will receive marketing approval. If our product candidates are associated with undesirable side effects or have other unexpected, unacceptable characteristics, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many investigational products that initially showed promise in clinical or earlier stage testing have later been found to cause side effects or other safety issues that prevented further development. Even if we receive regulatory approval for a candidate with a known safety risk that is described in the product's labeling, such an approved product may not achieve market acceptance by physicians, patients, third-party payors or others in the medical community, which would materially and adversely affect our business.

A breakthrough therapy designation by the FDA, even if granted for any of our product candidates, is no guarantee of a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek "breakthrough therapy" designation for certepetide and some or all of our current or future product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for other expedited approval programs, including priority review and accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to candidate products considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidate no longer meets the conditions for qualification. Thus, even though we intend to seek Breakthrough Therapy designation for certepetide and some or all of our future product candidates, there can be no assurance that we will receive or maintain breakthrough therapy designation.

A Fast Track designation by the FDA and other similar regulatory designations is no guarantee of a faster development, regulatory review or approval process.

If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track designation for a particular indication. We have been granted Fast Track designation for certepetide for the treatment of pancreatic cancer. We may seek Fast Track designation for other indications or for certain of our other current or future product candidates, but there is no assurance that the FDA will grant this status to any of our other proposed product candidates. Marketing applications filed by sponsors of products in Fast Track development may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether to grant Fast Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program or at any time.

Accelerated or provisional approval by the FDA or other relevant regulatory authority, even if granted for certepetide or future product candidates, is no guarantee of faster market introduction and it does not increase the likelihood that our product candidates will receive full marketing approval.

We plan to seek approval of certepetide and may seek approval of other current or future product candidates using an accelerated or provisional approval pathway available in many regulatory jurisdictions. A product candidate may be eligible for accelerated or provisional approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. As a condition of provisional approval, the regulatory authority may require the sponsor to perform adequate and well-controlled post-marketing clinical trials for the corresponding product/indication. Regulatory authorities may require that such studies be fully enrolled before the marketing application is approved. These confirmatory trials must be completed with due diligence.

Specifically, we may seek an early approval under the Australian Provisional Determination scheme. A product candidate may be eligible for a provisional determination in Australia if it is 1) intended to treat, prevent, or diagnose a life threatening or seriously debilitating condition, 2) for which there is preliminary clinical data demonstrating that the medicine is likely to provide a significant improvement in the efficacy or safety of treating the condition, 3) the preliminary clinical data suggests that the medicine is likely to provide a major therapeutic advance, and 4) sufficient evidence has been provided of a plan to submit comprehensive clinical data confirming the safety and efficacy of the medicine before the end of the six years provisional registration.

Failure to conduct required post-approval studies, or to confirm the predicted clinical benefit of the product during post-marketing studies, allows a regulatory authority to withdraw approval of the drug. In addition, in the United States, a company whose drug product is authorized for commercialization through the accelerated approval pathway must submit all promotional materials for products approved under the accelerated or provisional approval pathway to the FDA in advance of dissemination for potential agency comment, which could adversely impact the timing of the commercial launch of the product. Even if we do receive accelerated or provisional approval for one or more of our product candidates, we may not experience a faster development or regulatory review or approval process and receiving accelerated or provisional approval does not provide assurance of ultimate full regulatory approval.

Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates, which would prevent or delay regulatory approval and commercialization.

The clinical trials of our product candidates are, and the manufacturing and marketing of our products will be, subject to extensive and rigorous review and regulation by numerous governmental authorities in the United States and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. The risk/benefit profile required for product approval will vary depending on multiple factors and may include adequate duration of response, a delay in the progression of the disease, and/or an improvement in survival.

There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. There are precedents for companies in the biopharmaceutical

industry experiencing significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

Data from earlier studies conducted by third-party research institutions should not be relied upon as evidence that later or larger-scale clinical trials will succeed. Some future trials may have different patient populations than current studies and will test our product candidates in different indications, among other differences. In addition, our proposed manufacturing processes for our product candidates include what we believe will be process improvements that are not part of the production processes that were previously used in the earlier conducted clinical trials being conducted by the research institutions. Accordingly, our results with our product candidates may not be consistent with the results of those clinical trials.

In addition, even if such trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

We presently rely on contract manufacturing organizations to produce our product candidates at development and commercial scale quantities and have not yet qualified an alternate manufacturing supply, which could negatively impact our ability to meet any future demand for the products.

We do not presently have redundant suppliers for any of our product candidates. If the facilities where our product candidates are being manufactured and/or the associated equipment were significantly damaged or destroyed, or if there were other disruptions, delays or difficulties affecting manufacturing capacity, our planned and future clinical trials and commercial production for these product candidates would likely be significantly disrupted and delayed. It would be both time-consuming and expensive to replace this capacity with third parties, particularly since any new facility would need to comply with regulatory requirements.

Ultimately, if we are unable to supply our product candidates to meet commercial demand, were commercial approval to be obtained, whether because of processing constraints or other disruptions, delays or difficulties that we experience, our production costs could increase dramatically, and sales of the product and its long-term commercial prospects could be significantly damaged.

Also, as a result of the current geopolitical tensions and the conflict between Russia and Ukraine, the governments of the United States, the European Union, Japan and other jurisdictions have imposed sanctions on certain industry sectors and parties in Russia, as well as enhanced export controls on certain products and industries. These and any additional sanctions and export controls involving other countries, as well as any counter responses by the governments of Russia or other jurisdictions, could adversely affect, directly or indirectly, the global supply chain, with negative implications on the availability and prices of raw materials, energy prices, and our customers, as well as the global financial markets and financial services industry.

The commercial potential and profitability of our product candidates are unknown and subject to significant risk and uncertainty.

Even if we successfully develop and obtain regulatory approval for some or all of our product candidates, the market may not understand or accept the products, which could adversely affect both the timing and level of future sales. Ultimately, the degree of market acceptance of our product candidates (or any of our future product candidates) will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments or competitive products;
- the prevalence and severity of any side effects;
- the approval and marketing of other therapeutics against which our product candidates will compete;
- physician acceptance of our approach to our target disease indications, include the ease or difficulty of administering the future products;
- restrictions on how the product is distributed or used;
- the strength of our marketing and distribution support, including whether we receive support from any patient advocacy groups;
- the adequacy of product supply in light of complex manufacturing and distribution processes;

- the cost of the product, the reimbursement policies of government and third-party payors and our ability to obtain sufficient third-party coverage or reimbursement.

Even if we are successful in achieving sales of our product candidates, it is not clear to what extent, if any, the products will be profitable. In addition, changes in manufacturing processes or procedures generally require FDA or foreign regulatory authority review and approval prior to implementation. Thus, we may need to conduct additional non-clinical studies and clinical trials to support approval of any such changes. Furthermore, this review process could be costly and time-consuming and could delay or prevent the commercialization of product candidates.

We may enter into collaborations, strategic alliances, additional licensing arrangements, acquisitions, business combinations or other strategic transactions in the future, any of which could require us to incur significant expenses or issue securities that could significantly dilute the shares of our existing stockholders, and we may not realize the benefits of such alliances or licensing arrangements, acquisitions, business combinations or strategic transactions.

We may enter into collaborations, strategic alliances, additional licensing arrangements, acquisitions, business combinations or other strategic transactions with third parties that we believe are essential to product commercialization or will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that could significantly dilute the shares of our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and/or acquisition candidates and the negotiation process can be time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. Furthermore, there can be no assurance that our exploration of potential acquisitions, business combinations or strategic alternatives will result in us entering into or completing any transaction or that such transaction, if completed, will add to stockholder value.

Further, collaborations involving our product candidates, such as our collaborations with third-party research institutions, are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property and/or critical clinical data covering our products that results from our collaborating with them, and in such cases, we would not have the authority or exclusive right to utilize, publicly announce or commercialize such data or intellectual property.

As a result, if we enter into collaboration agreements and strategic partnerships or license our products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or licensing, we will achieve the economic return that justifies such a transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

If competitors develop and market products that are more effective, safer, and/or less expensive than our product candidates or offer other advantages, our commercial prospects will be limited or eliminated.

Our development programs now face, and will continue to face, intense competition from pharmaceutical, biopharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies engaged in drug discovery and development activities or funding, both in the United States and abroad. Some of these competitors are pursuing the development of drugs and other therapies that target the same diseases and conditions that we are targeting with our product candidates.

As a general matter, we also face competition from many other companies that are researching and developing product candidates in similar indications. Many of these companies have financial and other resources substantially greater than ours. In addition, many of these competitors have significantly greater experience in testing pharmaceutical and other therapeutic products, obtaining FDA and other regulatory approvals, and marketing and selling approved products in highly regulated commercial healthcare markets. If we ultimately obtain regulatory approval for any of our product candidates, we will also be competing with respect to manufacturing efficiency and marketing capabilities, areas in which we have limited or no commercial-scale experience. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated by our competitors. Competition may increase further as a result of advances made in the commercial applicability of our technologies and greater availability of capital for investment in these fields.

We conduct significant operations through our wholly-owned Australian subsidiary. If we lose our ability to operate in Australia, or if the subsidiary is unable to receive the research and development tax credit allowed by Australian regulations, our business and results of operations will suffer.

We develop certain of our programs in part through our wholly-owned Australian subsidiary, Lisata Therapeutics Australia Pty Ltd. Due to the geographical distance as well as our limited experience operating in Australia, we may not be able to efficiently or successfully monitor, develop or commercialize our products or programs in Australia, including conducting clinical trials. Furthermore, we have no assurance that the results of any clinical trials conducted for our product candidates in Australia will be accepted by the FDA or other foreign regulatory authorities for development and commercialization approvals. In addition, current Australian tax regulations provide for a refundable tax incentive between 43.5% to 48.5% (depending upon the income tax rate) for qualified research and development activities. If we are ineligible or unable to receive the research and development tax credit, or past credits are determined ineligible upon audit, or if we lose our ability to operate Lisata Therapeutics Australia Pty Ltd. in Australia, or the Australian government significantly reduces or eliminates the tax credit, our business and results of operation would be adversely affected. In the event we determine it advisable to stop operating through this subsidiary, we may be required to migrate such operations from this subsidiary to us. Any such action may be difficult and cause us to incur additional expenses, as well as give rise to tax liabilities for us or erode our tax attributes (such as tax credits or net operating losses).

We may be subject to significant product liability claims and litigation, including potential exposure from the use of our product candidates in human subjects, and our insurance may be inadequate to cover claims that may arise.

Our business exposes us to potential product liability risks inherent in the testing, processing and marketing of our products. Such liability claims may be expensive to defend and result in large judgments against us. We face an inherent risk of product liability exposure related to the testing of our current and any future product candidates in human clinical trials and will face an even greater risk with respect to any commercial sales of our products should they be approved. All our product candidates are in the clinical phase of development and therefore, relevant safety data are limited.

We will need to increase our insurance coverage whenever we begin commercializing product candidates. At that time, we may not be able to obtain or maintain product liability insurance on acceptable terms with adequate coverage or at all, or if claims against us substantially exceed our coverage, then our financial position could be significantly impaired.

Whether or not we are ultimately successful in any product liability litigation that may arise, such litigation could consume substantial amounts of our financial and managerial resources, decrease demand for our products and injure our reputation.

We seek to maintain errors and omissions, directors and officers, workers compensation and other insurance at levels we believe to be appropriate to our business activities. If, however, we were subject to a claim in excess of this coverage or to a claim not covered by our insurance and the claim succeeded, we would be required to pay the claim from our own limited resources, which would have a material adverse effect on our financial condition, results of operations and business. Additionally, liability or alleged liability could harm our business by diverting the attention and resources of our management and damaging our reputation.

We may be unable to retain key officers or employees or hire new key officers or employees needed to implement our business strategy and develop our products and businesses.

We are substantially dependent on the skills and efforts of current senior management for their management and operation skills, as well as for the implementation of our business strategy. In addition, our future success depends upon our ability to attract and retain additional qualified personnel (including medical, scientific, technical, commercial, business and administrative personnel) necessary to support our anticipated growth, develop our business, perform our contractual obligations to third parties and maintain appropriate licensure and compliance to applicable laws and regulations. There can be no assurance that we will be successful in attracting or retaining personnel required by us to continue to grow our operations. The loss of a key employee, the failure of a key employee to perform in his or her current position or our inability to attract and/or retain skilled employees, as needed, could result in our inability to continue to grow our business or to implement our business strategy, or may have a material adverse effect on our business, financial condition and operating results.

Our internal computer systems, or those used by our clinical investigators, clinical research organizations or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of development programs for our product candidates.

We rely on information technology systems to keep financial records, maintain laboratory and corporate records, communicate with staff and external parties and operate other critical functions. Any significant insufficiency, degradation or failure of these computer systems could cause us to lose our ability to operate effectively, accurately and/or efficiently. Despite the implementation of security measures, these internal computer systems and those used by our clinical investigators, clinical research organizations, and other contractors and consultants are vulnerable to damage from computer viruses, malware, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. The techniques that could be used by criminal elements or foreign governments to attack these computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. Furthermore, there is an increased risk of cybersecurity attacks by state actors. Russian, Chinese, Iranian, North Korean and other ransomware gangs have threatened or enacted increased hacking activity against critical infrastructure of many nations or organizations. Any such increase in such attacks on us and/or our third-party providers or other systems could adversely affect our network systems or other operations. While we have not experienced any such system failure, theft of information, accident or security breach to date, if such an event were to occur and cause interruptions in its operations, it could result in a material disruption of our clinical development activities and/or business operations. For example, the loss of clinical trial data from historical or future clinical trials could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. To the extent that any disruption, theft of information, or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the clinical development, and the future development of our product candidates could be delayed.

The increasing use of social media platforms presents new risks and challenges including but not limited to the dissemination of disinformation, false or misleading accusations, incorrect statements and/or inaccurate statements or data generated by individuals or through use of artificial intelligence.

Social media is increasingly being used to communicate information about clinical-stage product candidates and the diseases that our therapies are designed to treat. Social media practices in the pharmaceutical industry continue to evolve and regulations related to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients and others may use social media channels to comment on the effectiveness of a product candidate or to report an alleged adverse event. When such disclosures occur, we may fail to monitor and comply with applicable adverse event reporting obligations, or we may not be able to defend against political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face overly restrictive regulatory actions or incur other harm to our business.

RISKS RELATED TO MANUFACTURING OUR DEVELOPMENT PRODUCT CANDIDATES

Contract development and manufacturing organizations have a finite manufacturing capacity, which could inhibit the long-term growth prospects of our business.

We currently have manufacturing contracts to produce materials for our clinical trials. It is possible that future demand for our products could exceed existing manufacturing capacity. We expect that, as our own development programs progress and demand for therapeutics in the industry expands, it may become necessary or desirable for us to expand our manufacturing vendors for services and products in the future, which may require us to invest significant amounts of capital and to obtain regulatory approvals. If manufacturers are unable to meet our rising demand for products and services on a timely basis or unable to maintain cGMP compliance standards, then it is likely that the progress of our own programs will be impaired which could materially and adversely affect the overall success of our development programs.

Components of therapeutic products approved for commercial sale or used in clinical trials must be manufactured in accordance with cGMPs. In addition, manufacturers of therapeutic products may be required to modify their manufacturing processes from time to time in response to regulatory requests.

We will need to improve manufacturing efficiency at our contract manufacturers in order to establish cost of goods levels that will permit approved products to succeed commercially.

CMOs cannot provide assurances that they will be able to develop process enhancements that are acceptable to regulators or other comparable regulatory authorities, on a timely basis, on commercially reasonable terms, or at all, or that any expected improvement in profitability will be realized. If they are unsuccessful in their efforts to develop necessary improvements, we may be unable to develop commercially viable products, which would impair our ability to continue our operations.

We will rely on third parties to manufacture our clinical product supplies, and we may rely on third parties to produce and process our products, if approved.

We have no internal capacity to manufacture our development product candidates and have no assurance that we will continue to have access to manufacturers in our industry that can effectively make our development products or make them at an affordable, salable or otherwise commercially reasonable price or quantity.

We do not currently own any facility that may be used as a clinical scale manufacturing facility and expect to rely on outside vendors to manufacture supplies of our product candidates. We will need to negotiate and maintain contractual arrangements with these outside vendors for the supply of our product candidates, and we may not be able to do so on favorable terms. We have not yet caused any product candidates to be manufactured on a commercial scale and may not be able to do so for any of our product candidates.

The facilities used by our contract manufacturers to manufacture our products or future products must be approved by the FDA or other foreign regulatory authorities following inspections that will be conducted after we submit an application to the FDA or other foreign regulatory authorities. We may not control the manufacturing process of, and may be completely dependent on, our contract manufacturing partners for compliance with cGMPs and any other regulatory requirements of the FDA or other regulatory authorities for the manufacture of our product candidates. Beyond periodic audits and contractual arrangements, 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 a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or products or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Similarly, if any third-party manufacturers on which we will rely fail to manufacture quantities of our product candidates or products at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our business, financial condition and prospects could be materially and adversely affected.

RISKS RELATED TO SALES, MARKETING, AND COMPETITION

We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if approved, we may not be able to generate product revenue.

We currently have no sales, marketing or distribution capabilities and have no experience in marketing products. We intend to develop an in-house marketing organization and sales force in the future, which will require significant capital expenditure, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue arrangements with third-party sales, marketing, and distribution collaborators regarding the sales and marketing of our products, if approved. However, there can be no assurance that we will be able to establish or maintain such arrangements on favorable terms or if at all, or if we are able to do so, that these third-party arrangements will provide effective sales forces or marketing and distribution capabilities. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

We and our partners plan to seek regulatory approval of one or more of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including but not limited to:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other 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 taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- 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;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

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

Even if we obtain regulatory approval of our product candidates, our products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community.

Various factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages and risks of our product candidates over alternative treatments;
- our ability to demonstrate the advantages of our product candidates over other cancer medicines;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- the timing of market introduction of our product candidates as well as competitive products;

- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and governmental authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and governmental authorities;
- the relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue.

In addition, although our product candidates differ in certain ways from other approaches, serious adverse events or deaths in other clinical trials involving precision medicines, even if not ultimately attributable to our products or product candidates, could result in increased government regulation, unfavorable public perception and publicity, potential regulatory delays in the testing or licensing of our product candidates, stricter labeling requirements for those product candidates that are licensed, and a decrease in demand for any such product candidates.

Even if our products achieve market acceptance, it may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

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

The biotechnology and pharmaceutical industries utilize rapidly advancing technologies and are characterized by intense competition. While we believe that our scientific knowledge, technology and development expertise provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceuticals, specialty pharmaceuticals and biotechnology companies, academic institutions and government agencies, and public and private research institutes that conduct research, development, manufacturing and commercialization. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, regulatory approvals and product marketing than we do. Our competitors may compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

Product candidates that we successfully develop and commercialize may compete with existing therapies and new therapies that may become available in the future.

If our drug candidates are approved for the indications for which we are currently planning clinical trials, they will likely compete with existing drugs and other drugs that are currently in development. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products. Our competitors may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our products, which could result in our competitors establishing a strong market position before we are able to enter the market.

RISKS RELATED TO GOVERNMENT REGULATION

The development and commercialization of our product candidates are subject to extensive regulation by the FDA and other regulatory agencies in the United States and abroad, respectively, and the failure to receive regulatory approvals for our product candidates would likely have a material and adverse effect on our business and prospects.

Governmental authorities in the United States, at the federal, state and local level, and in other countries, extensively regulate, among other things, the research, development, testing, manufacture, including any manufacturing changes, packaging, storage, recordkeeping, labeling, advertising and promotion, distribution, marketing, import and export of pharmaceutical products, such as certepetide. The process of obtaining required regulatory approvals and the subsequent compliance with appropriate statutes and regulations requires the expenditure of substantial time and money, and there is no guarantee that we will successfully complete the steps needed to obtain regulatory approval of certepetide or any future

product candidates. There also are extensive and ongoing post-marketing compliance obligations to which we would be subject following FDA approval of any of our product candidates. In addition, these federal regulations may change, and our product candidates may be subject to new laws or regulations.

To date, we have neither applied for nor received regulatory approval to market any of our product candidates in any jurisdiction. If we seek approval of any of our product candidates, we will be required to submit to FDA and relevant other regulatory authorities, extensive non-clinical and clinical data supporting the safety and efficacy of such product candidates, as well as information about the manufacturing process and to undergo inspection of manufacturing facilities, among other things. The process of obtaining FDA and other regulatory approvals is expensive, typically takes many years and is subject to numerous risks and uncertainties. Changes in regulatory approval policies during the clinical research and development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application or may make it easier for our competitors to gain regulatory approval to enter the marketplace. Ultimately, the FDA and other regulatory agencies have substantial discretion in the approval/licensure process and may refuse to accept any application or may decide that our product candidate data are insufficient for approval without the submission of additional non-clinical, clinical or other time-consuming studies. In addition, varying agency interpretations of the data obtained from non-clinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Any of the following factors, among others, could cause regulatory approval for our product candidates to be delayed, limited or denied:

- the product candidates require further clinical testing to demonstrate safety and effectiveness before applications for marketing approval can be submitted to the FDA and other regulatory authorities;
- data obtained from animal testing and other non-clinical testing and clinical trials can be interpreted in different ways, and regulatory authorities may not agree with our respective interpretations or may require us to conduct additional testing;
- negative or inconclusive results or the occurrence of serious or unexpected adverse events during a clinical trial could cause us to delay and/or terminate development efforts for a product candidate; and/or
- the FDA and other regulatory authorities may require expansion of the size and scope of the clinical trials.

Any difficulties or failures that we encounter in securing regulatory approval for our product candidates would likely have a substantial adverse impact on our ability to generate product sales and could make any search for a collaborative partner more difficult.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems.

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product. The FDA may also require a REMS in order to approve a product candidate, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with applicable cGMP, GLP and GCP requirements. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation;
- revisions to the labeling, including limitation on approved uses or the addition of warnings, contraindications or other safety information, including boxed warnings;

- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- fines, warning letters or holds on clinical trials or product distribution and sale;
- refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. 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 and we may not achieve or sustain profitability.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. In particular, while the FDA permits the dissemination of truthful and non-misleading information about an approved product, a manufacturer may not promote a product for uses that are not approved by the FDA or other regulatory agencies as reflected in the product's approved labeling. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The DOJ and FDA have also requested that companies enter into consent decrees, corporate integrity agreements or permanent injunctions under which specified promotional conduct must be changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

We may be unsuccessful in our efforts to comply with applicable federal, state and international laws and regulations, which could result in government enforcement actions or impact our ability to secure regulatory approval of our product candidates.

Although we seek to conduct our business in compliance with applicable laws and regulations, these laws and regulations are exceedingly complex and often subject to varying interpretations. The biopharmaceutical industry is a topic of significant government interest, and thus the laws and regulations applicable to our business are subject to frequent change and/or reinterpretation. As such, there can be no assurance that we will be able, or will have the resources, to maintain compliance with all applicable biopharmaceutical and healthcare laws and regulations. Failure to comply with such biopharmaceutical and healthcare laws and regulations could result in significant enforcement actions, civil or criminal penalties, which along with the costs associated with such compliance or with enforcement of such biopharmaceutical and healthcare laws and regulations, may have a material adverse effect on our operations or may require restructuring of our operations or impair our ability to operate profitably.

cGMP regulations govern the manufacture, processing, packaging and holding of biopharmaceutical products. Any third-party manufacturers that prepare our products must comply with cGMP requirements including quality control, quality assurance and the maintenance of relevant records and documentation. They may be unable to comply with these cGMP requirements and with other national regulators and state and local regulatory requirements. These requirements may change over time and we or third-party manufacturers may be unable to comply with the revised requirements.

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 are subject to laws and regulations covering data privacy and the protection of personal information including health information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. In the United States, we may be subject to state security breach notification laws, state health information privacy laws and federal and state consumer protections laws which impose requirements for the collection, use, disclosure, and transmission of personal information. If we fail to comply

with applicable laws and regulations, we could be subject to penalties or sanctions, including criminal penalties if we knowingly obtain individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA or for aiding and abetting the violation of HIPAA. In addition, as various states, such as California, Virginia, Colorado, Connecticut, and Utah implement their own privacy laws and regulations, the interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, which may create complex compliance issues for us and potentially expose us to additional expense, adverse publicity and liability. Further, as regulatory focus on privacy issues continues to increase and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to our business could intensify.

Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. In May 2016, the European Union formally adopted the General Data Protection Regulation (“GDPR”), which applies to all EU member states from May 25, 2018, and replaced the EU Data Protection Directive. The regulation introduced stringent new data protection requirements in the European Union and substantial fines for breaches of the data protection rules. It has increased our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms ensuring compliance with the new EU data protection rules. The GDPR is a complex law and the regulatory guidance is still evolving, including with respect to how the GDPR should be applied in the context of clinical studies. Furthermore, many of the countries within the European Union are still in the process of drafting supplementary data protection legislation in key fields where the GDPR allows for national variation, including the fields of clinical study and other health-related information. These variations in the law may raise our costs of compliance and result in greater legal risks.

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

We are exposed to the risk of fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: a) comply with the regulations of the FDA and foreign regulatory authorities, provide true, complete and accurate information to the FDA and foreign regulatory authorities, b) comply with manufacturing standards we have established, c) comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or d) report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products, our potential exposure under such laws and regulations will increase significantly, and our costs associated with compliance with such laws and regulations are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing, and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the Federal False Claims Act. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the Federal False Claims Act (the “FCA”), which impose criminal and civil penalties, including through civil “qui tam” or “whistleblower” actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal healthcare programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay money to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an

obligation. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the Federal False Claims Act, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions;
- the federal Physician Payment Sunshine Act, created under the ACA and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, chiropractors and certain non-physician advanced practice practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting it from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices, or those of our partners or critical contractors, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant criminal, civil and administrative sanctions

including monetary penalties, damages, fines, disgorgement, individual imprisonment, and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if it becomes subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and it may be required to curtail or restructure our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Any action against us for violation of these laws, even if we successfully defend against them, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization.

Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that it will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that it will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also independently approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional non-clinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. 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. If we fail to comply with the regulatory requirements in international markets and/or 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.

Healthcare companies have been the subject of federal and state investigations, and we could become subject to such investigations in the future.

Both federal and state government agencies have heightened civil and criminal enforcement efforts. There are numerous ongoing investigations of healthcare companies, including drug, biologic and medical device companies, as well as their executives and managers. In addition, amendments to the Federal False Claims Act, including under healthcare reform, have made it easier for private parties to bring "*qui tam*" (whistleblower) lawsuits against companies under which the whistleblower may be entitled to receive a percentage of any money paid to the government. The Federal False Claims Act provides, in part, that an action can be brought against any person or entity that has knowingly presented, or caused to be presented, a false or fraudulent request for payment from the federal government, or who has made a false statement or used a false record to get a claim approved. The government has taken the position that claims presented in violation of the federal anti-kickback law or other healthcare-related laws, including laws enforced by the FDA, may be considered a violation of the Federal False Claims Act. Penalties include substantial fines for each false claim, plus three times the amount of damages that the federal government sustained because of the act of that person or entity and/or exclusion from the Medicare program. In addition, a majority of states have adopted similar state whistleblower and false claims provisions.

We are not aware of any government investigations involving any of our facilities or management. While we believe that we are in material compliance with applicable governmental healthcare laws and regulations, any future investigations of our business or executives could cause us to incur substantial costs, and result in significant liabilities or penalties, as well as damage to our reputation.

It is uncertain to what extent government, private health insurers, and third-party payors will approve coverage or provide reimbursement for the therapies and products to which our research and development relate. Availability for such reimbursement may be further limited by an increasing uninsured population and reductions in Medicare and Medicaid funding in the United States.

To the extent that healthcare providers cannot obtain coverage or reimbursement for our therapies and products, they may elect not to provide such therapies and products to their patients and, thus, may not need our services. Further, as cost containment pressures are increasing in the healthcare industry, government and private payors may adopt strategies designed to limit the amount of reimbursement paid to healthcare providers.

Similarly, the trend toward managed healthcare and bundled pricing for healthcare services in the United States, could significantly influence the purchase of healthcare services and products, resulting in lower prices and reduced demand for our therapeutic products under development.

We may receive a portion of our revenues from services rendered to patients enrolled in federal healthcare programs, such as Medicare, and we may also directly or indirectly receive revenues from federal healthcare programs. Federal healthcare programs are subject to changes in coverage and reimbursement rules and procedures, including retroactive rate adjustments. These contingencies could materially decrease the range of services covered by such programs or the reimbursement rates paid directly or indirectly for our products and services. To the extent that any healthcare reform favors the reimbursement of other therapies over our therapeutic products under development, such reform could affect our ability to sell any products for which we are able to obtain regulatory approval, which may have a material adverse effect on our revenues.

The limitation on reimbursement available from private and government payors may reduce the demand for, or the price of, our services, which could have a material adverse effect on our revenues. Additional legislation or regulation relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future which could adversely affect the revenues generated from the sale of our products and services.

Furthermore, overall funding for Medicare and Medicaid remains unpredictable and at the discretion of the U.S. government. Also, there remain a large number of people who do not have any form of healthcare coverage and who are not eligible for or enrolled in Medicare, Medicaid or other governmental programs. The extent to which any future healthcare reform may be successful in reducing the number of such uninsured is unclear, and the reduced funding of governmental programs and increase in uninsured populations could have a negative impact on the demand for our products and services that may be reimbursed by government and private payors.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within the U.S. Department of Health and Human Services (“HHS”). CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours. Reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European countries. Moreover, eligibility for reimbursement does not imply that any 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 not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products we may 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.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates from third-party 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 products and our overall financial condition.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we are eventually able to commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In order to obtain reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard-of-care drugs, including lower-priced generic versions of standard-of-care drugs. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Additionally, we and/or our collaborators may develop companion diagnostic tests for use with our product candidates. We, or our collaborators, may be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, once approved. Even if we obtain regulatory approval or clearance for such companion diagnostics, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates. Medicare reimbursement methodologies, whether under Part A, Part B, or clinical laboratory fee schedule may be amended from time to time, and we cannot predict what effect any change to these methodologies would have on any product candidate or companion diagnostic for which we or our collaborators receive approval. Our inability to promptly obtain coverage and adequate reimbursement from both third-party payors for the companion diagnostic tests that we develop and for which we or our collaborators obtain regulatory approval could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Legislation and legislative and regulatory proposals intended to contain healthcare costs may adversely affect our business.

The containment of healthcare costs has become a priority of federal and state governments and the prices of drug products have been a focus of this effort. For example, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. We expect that federal, state and local governments in the United States will continue to consider legislation directed at lowering the total cost of healthcare and prescription drugs. Individual U.S. states have increasingly passed legislation and implemented 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. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate PBMs and other members of the healthcare and pharmaceutical supply chain, an important decision that has led to more aggressive efforts by states in this area.

The U.S. Congress is currently considering numerous PBM reforms including diverse legislative proposals such as eliminating rebates; divorcing service fees from the price of a drug, discount, or rebate; prohibiting spread pricing; limiting administrative fees; requiring PBMs to report formulary placement rationale; promoting transparency. The Federal Trade Commission in mid-2022 also launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. Significant efforts to change the PBM industry as it currently exists in the United States may affect the entire pharmaceutical supply chain and the business of other stakeholders, including medical product developers like us.

On August 16, 2022, President Biden signed into the law the Inflation Reduction Act ("IRA"). Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the U.S. For example, under the IRA, a manufacturer of drugs or biological products covered by Medicare Parts B or D must pay a rebate to the federal government if their drug product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, CMS will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition, and starting for payment year 2028, CMS will begin negotiating drug prices for a select number of Part B drugs. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new authorities announcing the first round of negotiated prices for the first 10 drug products in August 2024, which will become applicable for payment year 2026. The second round of negotiated prices for 15 drug products was announced in November 2025. Ultimately, the IRA's impact on the biopharmaceutical industry in the United States remains uncertain, in part because of multiple ongoing lawsuits against CMS brought by large pharmaceutical companies and other stakeholders (e.g., the U.S. Chamber of Commerce).

It is uncertain whether and how future legislation or regulatory changes could affect prospects for our product candidates or what actions third-party payors may take in response to any such healthcare reform proposals or legislation. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures reforms, may prevent or limit our ability, or the ability of a commercial collaborator, to commercialize any of our future products that receive marketing approval as well as our ability to generate revenue and attain profitability.

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

In some countries, particularly the member states of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. In addition, there can be considerable pressure from governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries where we may seek to market our product candidates in the future, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidate to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, 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 government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Future legislative and regulatory proposals may materially impact the ability of the FDA and other regulatory agencies to operate as they have historically operated. We cannot be sure whether additional legislative changes or executive orders will be enacted, or whether any of the FDA's regulations, guidances or interpretations will be changed, or what the impact of such changes on the agency and its scientific review staff, if any, may be. For example, the FDA has experienced significant and rapid fluctuations in leadership and scientific review personnel, which may be key contributing factors in multiple reported delays in agency decision making on marketing applications and agency requests for additional data that are inconsistent with prior regulatory feedback. In addition, the next FDA user fee reauthorization package entered the stakeholder negotiation phase in mid-2025, and any agreement will be sent to Congress in early 2027 for purposes of initiating the legislative process. Reauthorization of the prescription drug user fee program would need to be finalized by Congress by the end of September 2027 in order to avoid a disruption in FDA's performance goals for activities supported by user fees assessed against industry.

In addition, disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, political disputes in Congress may result in a shutdown of the U.S. government, and in such cases certain regulatory agencies, such as the FDA and the SEC, would have to furlough employees and stop critical activities during that period. Moreover, government shutdowns or slowdowns can increase the time needed for an agency to complete its review or make final approvals or other administrative decisions. 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.

A variety of risks associated with operating our business internationally could materially adversely affect our business.

We plan to seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we, and any potential collaborators in those jurisdictions, will be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;
- differing coverage and reimbursement requirements in foreign countries;

- unexpected changes in tariffs, trade barriers, price and exchange controls, and other 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 taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign laws, such as the U.K. Anti-Bribery Act;
- 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;
- the continued threat of terrorism and the impact of military and other action, including military actions involving Russia and Ukraine, and others;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad, including as a result of pandemics or possible military actions and conflicts around the world; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our planned international operations may materially adversely affect our ability to attain or maintain profitable operations.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

We may be unable to obtain or maintain patent protection for our products and product candidates, which could have a material adverse effect on our business.

Our commercial success will depend, in part, on obtaining and maintaining patent protection for new technologies, product candidates, products and processes and successfully defending such patents against third-party challenges. To that end, we have filed patent applications and maintain issued patents intended to cover certain methods, uses and compositions relating to our products and product candidates. These patent applications may never result in the issuance of patents.

The patent positions in the pharmaceutical industry can be highly uncertain and involve complex legal, scientific and factual questions and recent court decisions have introduced significant uncertainty regarding the strength of patents in the industry. Moreover, the legal systems of some foreign countries do not favor the aggressive enforcement of patents and may not protect our intellectual property rights to the same extent as the laws of the United States. Any of the issued patents we own or license may be challenged by third parties and held to be invalid, unenforceable or with a narrower or different scope of coverage than what we currently believe, effectively reducing or eliminating protection we believed we had against competitors with similar products or technologies. If we ultimately engage in and lose any such patent disputes, we could be subject to competition and/or significant liabilities, we could be required to enter into third-party licenses or we could be required to cease using the disputed technology or product. In addition, even if such licenses are available, the terms of any license requested by a third party could be unacceptable or unaffordable to us.

Product development and approval timelines in the biotechnology industry are very lengthy. As such, it is possible that any patents that may cover an approved product may have expired at the time of commercialization or only have a short remaining period of exclusivity, thereby reducing the commercial advantages of the patent. In such case, we would then rely solely on other forms of exclusivity, such as regulatory exclusivity provided by the FD&C Act, which may provide less protection to our competitive position.

Litigation relating to intellectual property is expensive, time-consuming and uncertain, and we may be unsuccessful in our efforts to protect against infringement by third parties or defend ourselves against claims of infringement.

To protect our intellectual property, we may initiate litigation or other proceedings. In general, intellectual property litigation is costly, time-consuming, diverts the attention of management and technical personnel and could result in substantial uncertainty regarding our future viability, even if we ultimately prevail. Some of our competitors may be able to sustain the

costs of such litigation or other proceedings more effectively than we can because of their substantially greater financial resources. The loss or narrowing of our intellectual property protection, the inability to secure or enforce our intellectual property rights or a finding that we have infringed the intellectual property rights of a third party could limit our ability to develop or market our products and services in the future or adversely affect our revenues. Furthermore, any public announcements related to such litigation or regulatory proceedings could adversely affect the price of our common stock.

Third parties may allege that the research, development and commercialization activities we conduct infringe patents or other proprietary rights owned by such parties. While we do not believe any of our current activities infringe the rights of others, we have not conducted an exhaustive search or analysis of third-party patent rights to determine whether our pre-clinical or clinical research and development or activities may infringe or be alleged to infringe any third-party patent rights. If we are found to have infringed the patents of a third party, we may be required to pay substantial damages; we also may be required to seek from such party a license, which may not be available on acceptable terms, if at all, to continue our activities. A judicial finding of infringement or the failure to obtain necessary licenses could prevent us from commercializing our products, which would have a material adverse effect on our business, operating results and financial condition.

If we are unable to maintain our licenses, patents or other intellectual property we could lose important protections that are material to continuing our operations and our future prospects.

To obtain and maintain patent protection and licensing rights under certain of our license agreement, we must, among other things, ensure the timely payment of all applicable filing and maintenance fees. Any failure to do so could result in the loss of some or all of our rights to proprietary technology or the inability to secure or enforce intellectual property protection.

Additionally, our license agreements require us to meet certain diligence obligations in the development of the licensed products. Our failure to meet these diligence obligations could result in the loss of some or all of our rights, which could materially and adversely affect our business and future prospects.

On December 1, 2015, Cend entered into an Exclusive License Agreement (the “SBP License Agreement”) with the Sanford Burnham Prebys Medical Discovery Institute (“SBP”), a California not-for-profit, public benefit corporation based in San Diego, California. Pursuant to the SBP License Agreement, which we assumed in connection with the Merger, SBP licensed to Cend the exclusive right to use certain patents to further Cend’s research and development efforts relating to certepetide. Because we do not have the right to control the preparation, filing and prosecution of all of the patent applications, or to maintain the patents, covering certepetide, we cannot be certain that these patents and applications will be prosecuted, maintained and enforced in a manner consistent with the best interests of our business. If our licensors fail to maintain such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated and our right to develop and commercialize any products that are the subject of such licensed rights could be adversely affected. In addition to the foregoing, the risks associated with patent rights that we license from third parties will also apply to patent rights it may own in the future.

Further, pursuant to our license agreements, we may be held responsible for bringing actions against infringers. Certain of our license agreements could also require us to meet development thresholds to maintain the license, including establishing a set timeline for developing and commercializing products and minimum yearly diligence obligations in developing and commercializing the product. Disputes may also arise regarding intellectual property subject to a licensing agreement.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

If we fail to comply with our obligations under these license agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license.

If we are unable to obtain and maintain patent protection for our products and technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully partner and commercialize our products and technology may be adversely affected.

Our success depends on our ability to obtain and maintain patent protection in the United States and other countries with respect to proprietary product candidates and manufacturing technology. Our licensors have sought and we intend to seek to protect proprietary position by filing patent applications in the United States and abroad related to the novel technologies and product candidates that are vital to our business.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. For

example, in some cases, the work of certain academic researchers in the field of oncology could enter the public domain, which may compromise our ability to obtain patent protection for certain inventions related to or building upon such prior work. Consequently, we may not be able to obtain any such patent rights to prevent others from using our technology for, and developing and marketing competing products to treat, these indications. It is also possible that we will fail to identify patentable aspects of our research and development output prior to obtaining adequate patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of patent rights remain highly uncertain. Any pending and future patent applications may not result in patents being issued which protect the related technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of patents or narrow the scope of patent protection.

We may not be aware of all third-party intellectual property rights potentially relating to our targeted product candidates. Publications of discoveries in the scientific literature often lag the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in any owned or any licensed patents or pending patent applications, or that it was the first to file for patent protection of such inventions.

Even if the patent applications we license or may own in the future do issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent key patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and key patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which may impair our ability to stop others from using or commercializing similar or identical technology and products; or limit the duration of the patent protection of our technology and product candidates. 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 intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Further, in the event we breach the terms of the SBP License Agreement, we could lose the ability to continue the development and potential commercialization of certepetide, and our operations and profitability will be significantly negatively impacted.

If we fail to comply with our obligations in any future agreements under which we may license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with future licensors, we could lose license rights that are important to our business.

In the future, we may be party to license or collaboration agreements with third parties to advance our research or allow commercialization of product candidates. Such future agreements may impose numerous obligations, such as development, diligence, payment, commercialization, funding, milestone, royalty, sublicensing, insurance, patent prosecution, enforcement and other obligations on us and may require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. In spite of our best efforts, future licensors might conclude that we have materially breached future license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technologies covered by these license agreements.

Any termination of these licenses, or if the underlying patents fail to provide the intended exclusivity, could result in the loss of significant rights and could harm our ability to commercialize our product candidates, and competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and it may be required to cease our development and commercialization of certain of our product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Disputes may also arise between us and our future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;

- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property rights of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the priority of invention of any patented technology; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners.

In addition, the agreements under which we may license intellectual property or technology from third parties in the future are likely to be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we may license in the future prevent or impair our ability to maintain future licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

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

We may discover that we need to obtain additional rights to the foundational IP associated with the product candidates we plan to develop, manufacture and market. If this occurs, we intend to license or purchase the rights to those candidates, which may or may not prove successful at all, or on acceptable terms. If our programs require the use of proprietary rights held by third parties, such as academic institutions, the growth of our business will critically depend on our ability to acquire, in-license or use these proprietary rights, which may not prove possible on acceptable terms. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. If we are unable to license or acquire third-party intellectual property rights on terms that would allow us to execute our business plan, your investment may be lost.

We may collaborate with non-profit and academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions would provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to it. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our product candidates, identify other candidates, or to develop or license replacement technology, none of which may be feasible on a technical or commercial basis, especially with our limited resources. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could critically harm our business.

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our licensed patents and/or applications and any patent rights we may own in the future. We may rely on our outside counsel or licensing partners to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We plan to employ reputable law firms and other professionals to help us comply, but we will also be dependent on our licensors to take the necessary action to comply with these requirements with respect to their licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance

with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could irreparably harm our business.

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

We anticipate that many of our consultants or advisors will currently be, or were previously, employed at universities, industry service providers (e.g., CDMOs, CROs, CDOs, etc.), or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

Presently we have two pending patent applications in the United States and thirteen pending patent applications outside the United States. Because additional product candidates may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights.

Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. Similarly, efficient production or delivery of our product candidates may also require specific compositions or methods, and the rights to these may be owned by third parties. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we are able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be nonexclusive, thereby giving our competitors access to the same technologies licensed to it. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Moreover, the molecules that will be used with our product candidates may be covered by the intellectual property rights of others.

Additionally, we sometimes collaborate with academic institutions to accelerate our clinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program and allowing third parties to compete with us. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that it may seek to acquire. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program, and our business, results of operations, financial condition and prospects could suffer.

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

Depending upon the timing, duration and specifics of any FDA marketing approval of any of our current or future product candidates, one or more U.S. patents we may own or in-license in the future may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because

of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is shorter than what we request, our competitors may obtain approval of competing products following expiration of any patents that issue from our patent applications, and our business, financial condition, results of operations, and prospects could be materially harmed.

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

Our trademarks or trade names may be challenged, infringed, diluted, circumvented or declared generic or determined to be infringing on other marks. We intend to rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During the trademark registration process, we may receive Office Actions from the USPTO objecting to the registration of our trademarks. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to obtain a registered trademark or establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

If we are unable to protect the confidentiality of trade secrets, our competitive position could be impaired.

A significant amount of our technology, especially regarding manufacturing processes, is unpatented and is maintained as trade secrets and /or know-how. We expend significant energy, resources and know-how in an effort to protect these trade secrets and know-how, including through the use of confidentiality agreements. Even so, improper use or disclosure of our confidential information could occur, and in such case, adequate remedies may not exist. The disclosure of trade secrets and know-how could impair our competitive position. Although we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, trade secrets can be difficult to protect and we have limited the protection of trade secrets used by our collaborators and suppliers. We cannot be certain that we have or will obtain these agreements in all circumstances and cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary information.

Moreover, any of these parties might breach the agreements and intentionally or inadvertently disclose our trade secret information and we may not be able to obtain adequate remedies for such breaches. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights and trade secrets to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition, results of operations and future prospects.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. For example, significant elements, including aspects of drug manufacturing processes, experiments to validate mechanisms and pharmacology, drug design, and related processes, are based on unpatented trade secrets that are not publicly disclosed. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us.

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. In the case of employees, the agreements provide that all inventions conceived by

the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. Although we require all of our employees to assign their inventions to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In certain countries, patent holders may be required to grant compulsory licenses, which would likely have a significant and detrimental effect on any future revenues in such country.

Many countries, including some countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, most countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may be limited to monetary relief and may be unable to enjoin infringement, which could materially diminish the value of the patent. Compulsory licensing of life-saving products is also becoming increasingly common in developing countries, either through direct legislation or international initiatives. Such compulsory licenses could be extended to our product candidates, which may limit our potential revenue opportunities, including with respect to any future revenues that may result from our product candidates.

Changes to U.S. patent law may have a material adverse effect on our intellectual property rights.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs, and may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and any licensed patents. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the Leahy-Smith Act), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. The U.S. 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. Depending on future actions by the U.S. Congress, the U.S. courts, the U.S. Patent and Trade Office (the “USPTO”) and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents, trademarks and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, and reexamination proceedings before the USPTO and corresponding foreign patent offices and trademark violations. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products and services. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our products and services may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to devices, materials, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of our products and services. We have conducted freedom to operate analyses with respect to only certain of our products and services, and therefore we do not know whether there are any third-party patents that would impair our ability to commercialize these products and services. We also cannot guarantee that any of our analyses are complete and thorough, nor can we be sure that we have identified each and every patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of our products and services. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our products or services may inadvertently infringe upon.

In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover aspects of our products or services, the holders of any such patents may be able to block our ability to commercialize such products or services unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our products or services. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

RISKS RELATED TO OUR RELIANCE ON THIRD PARTIES

We may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such collaborations, alliances, or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety, potency, purity and efficacy and obtain marketing approval.

Further, collaborations involving our product candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization of our product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own critical clinical data or intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the authority or exclusive right to utilize or publicly announce, or commercialize such data or intellectual property, respectively.

As a result, if we enter into additional collaboration agreements and strategic partnerships or licenses our product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

Our manufacturing process needs to comply with regulatory authority regulations relating to the quality and reliability of such processes. Any failure to comply with relevant regulations could result in delays in or termination of our clinical programs and suspension or withdrawal of any regulatory approvals.

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

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

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

RISKS RELATED TO MANAGING GROWTH AND EMPLOYEE MATTERS

We may need to grow the size or change the structure of our organization, and may experience difficulties in managing this growth or change.

As of December 31, 2025, we had 21 full-time employees. We may need to hire new employees to conduct our research and development, administrative or business activities in the future. Any delay in hiring such new employees could result in delays in our research and development activities and would harm our business. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial and other personnel, as well as additional facilities to expand our operations. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, managing, maintaining and motivating additional employees;
- advanced and/or expanded applications of our drug discovery and development platform;
- managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- maintaining and/or improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of our attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of regulatory approval, clinical trial execution and manufacturing. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, or we are not able to effectively build out new facilities to accommodate this expansion, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the planned clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical 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 or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants, clinical investigators and related institutions;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate;
- a decline in share price; and
- increased insurance costs or the inability to secure sufficient relevant insurance coverage.

Failure to obtain or retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Although we have clinical trial insurance, our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

GENERAL RISK FACTORS

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with storage or disposal of biological, hazardous or radioactive materials.

Data collection is governed by restrictive regulations governing the use, storage, processing and transfer of personal information.

The collection, use, storage, disclosure, transfer, or other processing of personal data is subject to the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosure to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action. The CCPA went into effect on January 1, 2020, and the California Attorney General commenced enforcement actions for violations beginning July 1, 2020. The CCPA was amended on September 23, 2018, and it remains unclear what, if any, further modifications will be made to this legislation or how it will be interpreted. As currently written, the CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business.

We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure.

We rely on information technology systems that we or our third-party providers operate to process, transmit and store electronic information in our day-to-day operations. In connection with our product discovery efforts, we may collect and use a variety of personal data, such as name, mailing address, email addresses, phone number and clinical trial information. A successful cyberattack could result in the theft or destruction of intellectual property, data, or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under

state (e.g., state breach notification laws), federal (e.g., HIPAA, as amended by HITECH), and international law (e.g., the GDPR) and may cause a material adverse impact to our reputation, affect our ability to conduct new studies and potentially disrupt our business.

In addition, the computer systems of various third parties on which we rely, and other contractors, consultants and law and accounting firms, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third-party providers could have difficulty preventing, detecting and controlling such cyberattacks and any such attacks could result in losses described above as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by such third parties to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business.

RISKS RELATED TO OUR COMMON STOCK

Our stock price has been, and will likely continue to be, highly volatile.

The market price of our common stock has been, and in the future may continue to be, highly volatile. For example, from January 1, 2025 through March 12, 2026 our common stock traded as low as \$1.81 per share and as high as \$5.07 per share.

The market price for our common stock is highly dependent on, among other things, stock market conditions in general, the type and distribution of investors that make up our shareholder base, our clinical development efforts and the growth of our business in general, the amount of our available cash and investments and our level of cash utilization as well as the public understanding and perception of public announcements we make. Future events could increase the volatility seen in our common stock and ultimately cause a significant decline in the price of our common stock and ultimately impact our ability to raise additional capital in the future. These events could include the following, among others:

- positive announcements by competitors;
- low levels of trading volume for our shares;
- capital-raising or other transactions that are, or may in the future be, dilutive to existing stockholders or that involve the issuance of debt securities;
- delays in our clinical trials, significant issues associated with any aspect of our development efforts (e.g., failed manufacturing or negative clinical trial results) or adverse regulatory decisions relating to our product candidates;
- adverse fluctuations in our operating results or financial results that otherwise fall below the market's expectations;
- disappointing developments concerning our product candidates;
- incorrect or misleading reports about our products, data and/or company;
- positive developments concerning our product candidates that lead to the need for additional capital to complete the development process; and
- legal challenges, disputes and/or other adverse developments impacting our patents or other proprietary rights that protect our products.

In addition, broader external events, such as news concerning economic or market conditions in the general economy or within our industry, the activities of our competitors, changes (or the threat of changes) in U.S. or foreign government regulations impacting the life sciences industry or the movement of capital into or out of our industry, are likely to affect the price of our common stock. Geopolitical events, including the continued threat of terrorism and the impact of military and other action, including but not limited to military actions involving Russia and Ukraine as well as Israel and Gaza, could impact our stock price as well. There can be no assurance that the market price of our common stock will not continue to fluctuate or decline significantly in the future.

We may fail to comply with the continued listing requirements of the Nasdaq Capital Market, such that our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

Our common stock is listed for trading on the Nasdaq Capital Market. We must satisfy Nasdaq's continued listing requirements, including, among other things, a minimum closing bid price requirement of \$1.00 per share for 30 consecutive business days (the "Minimum Bid Price Requirement"). We have in the past been notified by Nasdaq that we were not in compliance with the Minimum Bid Price Requirement, and while we have regained compliance, there can be no assurance that we will remain compliant with the Minimum Bid Price Requirement or any other Nasdaq continued listing requirements.

A delisting of our common stock from Nasdaq could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees and fewer business development opportunities.

In addition to potential dilution associated with potential future fundraising and strategic transactions, we currently have securities outstanding that are exercisable for our common stock, which could result in significant additional dilution and downward pressure on our stock price.

As of December 31, 2025, there were 8,833,875 shares of our common stock outstanding. In addition, there were outstanding stock options, restricted stock units and warrants representing the potential issuance of an additional 3,105,000 shares of our common stock. The issuance of these shares in the future would result in significant dilution to our current stockholders and could adversely affect the price of our common stock and the terms on which we could raise additional capital. In addition, the issuance and subsequent trading of shares could cause the supply of our common stock available for purchase in the market to exceed the purchase demand for our common stock. Such supply in excess of demand could cause the market price of our common stock to decline.

Provisions in our amended and restated certificate of incorporation and by-laws and Delaware law may inhibit a takeover of us, which could limit the price investors might be willing to pay in the future for our common stock and could entrench management.

Our amended and restated certificate of incorporation and by-laws contain provisions that may discourage unsolicited takeover proposals that stockholders may consider to be in their best interests. Our board of directors is divided into three classes, each of which will generally serve for a term of three years with only one class of directors being elected in each year. As a result, at a given annual meeting only a minority of the board of directors may be considered for election. Since our staggered board of directors may prevent our stockholders from replacing a majority of our board of directors at any given annual meeting, it may entrench management and discourage unsolicited stockholder proposals that may be in the best interests of stockholders. Moreover, our board of directors has the ability to designate the terms of and issue new series of preferred stock without stockholder approval.

We are also subject to anti-takeover provisions under Delaware law, which could delay or prevent a change of control. Together, these provisions may make the removal of management difficult and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our securities.

Failure to maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business and stock price.

During the course of testing our disclosure controls and procedures and internal control over financial reporting, we may identify and disclose material weaknesses or significant deficiencies in internal control over financial reporting that will have to be remedied. Implementing any appropriate changes to our internal control may require specific compliance training of our directors, officers and employees, entail substantial costs to modify our existing accounting systems, and take a significant period of time to complete. Such changes may not, however, be effective in maintaining the adequacy of our internal control over financial reporting, and any failure to maintain that adequacy or inability to produce accurate financial statements on a timely basis could result in our financial statements being unreliable, increase our operating costs and materially impair our ability to operate our business.

Failure to achieve and maintain effective internal control over financial reporting could result in a loss of investor confidence in our financial reports and could have a material adverse effect on our stock price. Additionally, failure to maintain effective internal control over our financial reporting could result in government investigation or sanctions by regulatory authorities.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 1C. CYBERSECURITY.

Cybersecurity

We recognize the critical importance of maintaining the trust and confidence of partners, shareholders, government agencies and employees toward our business and are committed to protecting the confidentiality, integrity and availability of our business operations and systems. Our board of directors is actively involved in oversight of our risk management activities, and cybersecurity represents an important element of our overall approach to risk management. Our cybersecurity policies, standards, processes and practices are based on recognized frameworks established by the National Institute of Standards and Technology (“NIST”) and other applicable industry standards. In general, we seek to address cybersecurity risks through a comprehensive, cross-functional approach that is focused on preserving the confidentiality, security and availability of the information that we collect and store by identifying, preventing and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur.

Cybersecurity Risk Management and Strategy

We face risks related to cybersecurity such as unauthorized access, cybersecurity attacks and other security incidents, including as perpetrated by hackers and unintentional damage or disruption to hardware and software systems, loss of data, and misappropriation of confidential information. To identify and assess material risks from cybersecurity threats, we maintain a comprehensive cybersecurity program to ensure our systems are effective and prepared for information security risks, including regular oversight of our programs for security monitoring for internal and external threats to ensure the confidentiality and integrity of our information assets. We employ a range of tools and services, including regular network and endpoint monitoring, audits, vulnerability assessments, penetration testing, and tabletop exercises. As discussed in more detail under “Cybersecurity Governance” below, our audit committee provides oversight of our cybersecurity risk management and strategy processes.

We also identify our cybersecurity threat risks by comparing our processes to standards set by the NIST as well as by engaging experts to attempt to infiltrate our information systems. To provide for the availability of critical data and systems, maintain regulatory compliance, manage our material risks from cybersecurity threats, and protect against and respond to cybersecurity incidents, we undertake the following activities:

- monitor emerging data protection laws and implement changes to our processes that are designed to comply with such laws;
- through our policies, practices and contracts (as applicable), require employees, as well as third parties that provide services on our behalf, to treat confidential information and data with care;
- employ technical safeguards that are designed to protect our information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, anti-malware functionality and access controls, which are evaluated and improved through vulnerability assessments and cybersecurity threat intelligence;
- provide regular, mandatory training for our employees and contractors regarding cybersecurity threats as a means to equip them with effective tools to address cybersecurity threats, and to communicate our evolving information security policies, standards, processes and practices;
- conduct regular phishing email simulations for all employees and contractors with access to our email systems to enhance awareness and responsiveness to possible threats;
- conduct cybersecurity management and incident training for employees involved in our systems and processes that handle sensitive data;
- run tabletop exercises to simulate a response to a cybersecurity incident and use the findings to improve our processes and technologies;
- leverage the NIST incident handling framework to help us identify, protect, detect, respond and recover when there is an actual or potential cybersecurity incident; and

- carry cyber liability insurance that provides protection against the potential losses arising from a cybersecurity incident.

Our incident response plan coordinates the activities we take to prepare for, detect, respond to and recover from cybersecurity incidents, which include processes to triage, assess severity for, escalate, contain, investigate and remediate the incident, as well as to comply with potentially applicable legal obligations and mitigate damage to our business and reputation.

As part of the above processes, we may engage with assessors, consultants, auditors, and other third-parties, including by having a third-party review our cybersecurity program to help identify areas for continued focus, improvement and/or compliance.

Our processes also address cybersecurity threat risks associated with our use of third-party service providers who have access to patient and employee data or our systems. In addition, cybersecurity considerations affect the selection and oversight of our third-party service providers. We perform diligence on third parties that have access to our systems, data or facilities that house such systems or data. Additionally, we generally require those third parties that could introduce significant cybersecurity risk to us to agree by contract to manage their cybersecurity risks in specified ways, and to agree to be subject to cybersecurity audits, which we conduct as appropriate.

We describe how risks from cybersecurity threats are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition, under the heading, *“We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure,”* which disclosures are incorporated herein by reference. In the last three fiscal years, we have not experienced any material cybersecurity incidents.

Cybersecurity Governance

Cybersecurity is an important part of our risk management processes and an area of focus for our board of directors and management. In general, the audit committee of our board of directors oversees risk management activities designed and implemented by our management, and considers specific risks, including, for example, risks associated with our strategic plan, business operations, and capital structure. Our board of directors executes its oversight responsibility for risk management both directly and through delegating oversight of certain of these risks to its committees, and our board of directors has authorized our audit committee to oversee risks from cybersecurity threats.

At least quarterly, our audit committee receives an update from management of our cybersecurity threats and strategy processes covering topics such as data security posture, results from third-party assessments, progress towards pre-determined risk-mitigation-related goals, our incident response plan, and material cybersecurity threat risks or incidents and developments, as well as the steps management has taken to respond to such risks. In such sessions, our audit committee generally receives materials that include a cybersecurity update and other materials discussing current and emerging material cybersecurity threat risks, and describing our ability to mitigate those risks, as well as recent developments, evolving standards, technological developments and information security considerations arising with respect to our peers and third parties, and discusses such matters with our Chief Information Officer. Our audit committee also receives prompt and timely information regarding any cybersecurity incident that meets established reporting thresholds, as well as ongoing updates regarding any such incident until it has been addressed.

Members of our audit committee are also encouraged to regularly engage in conversations with management on cybersecurity-related news events and discuss any updates to our cybersecurity risk management and strategy programs. Material cybersecurity threat risks are also considered during separate board meeting discussions of important matters like enterprise risk management, operational budgeting, business continuity planning, mergers and acquisitions and other relevant matters.

Our cybersecurity risk management and strategy processes, which are discussed in greater detail above, are led by our Chief Information Officer and Data Protection Officer. This individual has over 30 years of prior work experience in various roles involving managing information security, developing cybersecurity strategy, implementing effective information and cybersecurity programs (nationally and globally), as well as several relevant degrees and certifications, including a Bachelors and Master’s Degree focusing in Computer Science, along with cybersecurity leadership, computer security, forensics, and technology certifications earned over the years. This management team member is informed about and monitors the prevention, mitigation, detection, and remediation of cybersecurity incidents through their management of, and participation in, the cybersecurity risk management and strategy processes described above, including the operation of our incident response plan. As discussed above, this management team member reports to the audit committee of our board of directors about cybersecurity threat risks, among other cybersecurity related matters, on a quarterly basis.

ITEM 2. PROPERTIES.

Our corporate headquarters are in Basking Ridge, New Jersey and although our lease expired on September 30, 2025 we, based on prior understanding with the building's management, continue to occupy a portion of office space in the building. We are seeking a new corporate space as a result of the building recently falling into receivership (and pending sale).

ITEM 3. LEGAL PROCEEDINGS.

From time to time, we are subject to legal proceedings and claims, either asserted or unasserted, that arise in the ordinary course of business. While the outcome of pending claims cannot be predicted with certainty, we do not believe that the outcome of any pending claims will have a material adverse effect on our financial condition or operating results.

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 for Our Common Equity

Our common stock trades on The Nasdaq Capital Market under the symbol “LSTA.”

Holders

As of March 12, 2026, there were approximately 322 holders of record of our common stock. The number of record holders was determined from the records of our transfer agent and does not include beneficial owners of our common stock whose shares are held in the names of various security brokers, dealers, and registered clearing agencies.

Dividends and Dividend Policy

We have not paid cash dividends on our common stock. The holders of our common stock are each entitled to receive dividends when and if declared by the board of directors out of funds legally available therefore, subject to the terms of any outstanding series of preferred stock. We intend to retain any future earnings to fund the development and growth of our business, and therefore we do not anticipate paying any cash dividends on our common stock in the foreseeable future.

Equity Compensation Plan Information

The following table provides information as of December 31, 2025 regarding shares of our common stock that may be issued under our existing equity compensation plans, including our 2018 Equity Incentive Compensation Plan (the “2018 Plan”), our 2015 Equity Compensation Plan (the “2015 Plan”), our 2009 Stock Option and Incentive Plan (the “2009 Plan”), and our amended 2017 Employee Stock Purchase Plan (the “Amended 2017 ESPP”).

Equity Compensation Plan Information			
	Number of securities to be issued upon exercise of outstanding options (1)	Weighted Average exercise price of outstanding options and rights	Number of securities remaining available for future issuance under equity compensation plan (excluding securities referenced in column (a))
Equity compensation plans approved by security holders (2)	1,502,881	\$6.17	478,010 (3)
Equity compensation plans not approved by security holders	0	—	0
Total	1,502,881	\$6.17	478,010 (3)

(1) Includes stock options only; does not include purchase rights accruing under the Amended 2017 ESPP Plan because the purchase price (and therefore the number of shares to be purchased) will not be determined until the end of the purchase period.

(2) Consists of the 2018 Plan, the 2015 Plan, the 2009 Plan, and the Amended 2017 ESPP.

(3) Includes shares available for future issuance under the 2018 Plan and the Amended 2017 ESPP.

Recent Sales of Unregistered Securities

None.

ITEM 6. [RESERVED].

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Cautionary Note Regarding Forward-Looking Statements" herein. The following discussion should be read in conjunction with our consolidated financial statements and related notes thereto included elsewhere in this Annual Report.

Overview

We are a clinical-stage pharmaceutical company dedicated to the discovery, development, and commercialization of innovative therapies for the treatment of solid tumors and other serious diseases. Our investigational product, certepetide (formerly known as LSTA1 or CEND-1), is designed to activate a novel uptake pathway (the C-end rule active transport mechanism) that allows co-administered or tethered (i.e., molecularly bound) anti-cancer drugs to target and penetrate solid tumors more effectively. Certepetide actuates this active transport system in a tumor-specific manner, resulting in systemically co-administered anti-cancer drugs more efficiently penetrating and accumulating in the tumor, while normal tissues are expected to remain unaffected. Certepetide has also been shown to modify the tumor microenvironment ("TME") by reducing T-regulatory cells and augmenting cytotoxic T cells, thereby making tumors more susceptible to immunotherapies while also inhibiting the metastatic cascade (i.e., the spread of cancer to other parts of the body). We, our collaborators and other researchers have amassed and continue to amass significant non-clinical data demonstrating enhanced delivery of a range of existing and emerging anti-cancer therapies, including chemotherapeutics, immunotherapies, and RNA-based therapeutics. In addition, certain preclinical data using certepetide in combination with antibody drug conjugates (ADCs) has been generated as part of our research collaboration with Catalent. These data were presented at a scientific meeting during the fourth quarter of 2025. To date, certepetide has also demonstrated favorable safety, tolerability and activity in completed and ongoing clinical trials designed to enhance delivery of standard-of-care chemotherapy, with and without added immunotherapy, for pancreatic cancer. Certepetide is or has been the subject of several Phase 2 clinical studies globally in a variety of solid tumor types, including metastatic pancreatic ductal adenocarcinoma (mPDAC), cholangiocarcinoma, appendiceal cancer, colon cancer and glioblastoma multiforme in combination with a variety of anti-cancer regimens.

Our leadership team has amassed many decades of collective biopharmaceutical and pharmaceutical product development experience across a variety of therapeutic categories and at all stages of development from preclinical through to product registration and launch. Our goal is to develop and commercialize products that address important unmet medical needs.

Recent Developments

Proposed Acquisition by Kuva Labs Inc.

On March 6, 2026, we entered into the Merger Agreement, pursuant to which, and upon the terms and subject to the conditions thereof, Purchaser will commence a tender offer to purchase all of our issued and outstanding shares of common stock in exchange for (i) \$5.00 per share, net to the seller in cash, without interest, but subject to any applicable withholding of taxes (the "Closing Amount") plus (ii) one non-tradeable CVR, which represents the contractual right to receive a contingent cash payment of \$1.00 per CVR if the Milestone is met as further described in the CVR Agreement. If certain conditions are satisfied and the Offer is consummated, Kuva would acquire any remaining shares for the Offer Price by a merger of Purchaser with and into us. Following completion of the transaction, we will become part of Kuva, a privately-held company, and our common stock will be delisted from Nasdaq. We will also apply to deregister our common stock and cease to be a reporting company under the United States Securities Exchange Act of 1934, as amended. Under the Merger Agreement, the Offer and the Merger will be subject to customary closing conditions for a transaction of this nature. Kuva will be required to close on the Offer so long as there shall be validly tendered a number of Shares that represents (and will represent immediately following the consummation of the Offer) at least a majority of the aggregate voting power of all Shares then outstanding. We cannot predict whether and when the conditions to closing will be satisfied. Until these conditions are satisfied and we and Kuva complete the proposed transaction, our business, operating results and financial condition are exposed to certain risks due to the effect of the pending proposed transaction. Refer to Item 1A. "Risk Factors" for a summary of risks related to the proposed transaction.

Termination of Qilu Exclusive License and Collaboration Agreement

On January 23, 2026, we and Qilu Pharmaceutical Co., Ltd. (“Qilu”) entered into a Mutual Termination Agreement (the “Termination Agreement”) relating to the Exclusive License and Collaboration Agreement between us (formerly Cend Therapeutics, Inc. (“Cend”)) and Qilu, relating to the research, development and commercialization of certepetide (formerly known as CEND-1), dated February 11, 2021, as amended on April 26, 2021, and further amended by the Side Letter Agreement, dated November 10, 2023 (collectively the “License and Collaboration Agreement”).

Previously, Cend (which was subsequently acquired by us) and Qilu entered into the License and Collaboration Agreement, pursuant to which we granted Qilu a royalty-bearing exclusive license for the research, development and commercialization of certepetide in the Greater China territory (including Mainland China, Hong Kong, Macau, and Taiwan). Pursuant to the License and Collaboration Agreement, we were eligible to receive up to \$200 million in development and commercial milestone payments and royalties ranging from 10% to 15% on licensed product sales. In consideration for the license, Qilu made an upfront payment of \$10.0 million to Cend, which was recognized as revenue by Cend prior to our acquisition of Cend on September 15, 2022 (the “Cend Merger”). In addition, Cend received and recognized as revenue a \$5.0 million development milestone prior to the Cend Merger. We have not received any additional development and commercial milestone payments since the Cend Merger.

Pursuant to the Termination Agreement, the License and Collaboration Agreement is terminated, effective as of January 23, 2026, and is no longer in effect, except that the termination does not relieve the parties from obligations under the License and Collaboration Agreement that accrued prior to the termination and certain other provisions expressly indicated to survive the termination.

Results of Operations

Year Ended December 31, 2025 Compared to Year Ended December 31, 2024

The following table summarizes our results of operations for the years ended December 31, 2025 and 2024:

	Year Ended December 31,		Change
	2025	2024	
Revenue	\$ 170	\$ 1,000	\$ (830)
Operating Expenses:			
Research and development	7,949	11,334	(3,385)
General and administrative	10,430	12,075	(1,645)
Total operating expenses	18,379	23,409	(5,030)
Loss from operations	(18,209)	(22,409)	4,200
Total other income	661	1,626	(965)
Benefit from income taxes	(962)	(798)	164
Net loss	\$ (16,586)	\$ (19,985)	\$ 3,399

Overall, net losses were \$16.6 million and \$20.0 million for the years ended December 31, 2025 and 2024, respectively.

Revenue

Revenue totaled \$0.2 million and \$1.0 million for the years ended December 31, 2025 and 2024, in connection with certain upfront license fees in the current year and the Exclusive License and Collaboration Agreement with Kuva in the prior year.

Operating Expenses

For the year ended December 31, 2025, operating expenses totaled \$18.4 million compared to \$23.4 million for the year ended December 31, 2024, representing a decrease of \$5.0 million or 21.5%.

Operating expenses comprise the following:

- Research and development expenses were approximately \$7.9 million for the year ended December 31, 2025, compared to \$11.3 million for the year ended December 31, 2024, representing a decrease of approximately \$3.4 million, or 29.9%. This was primarily due to a reduction in Clinical department expenses as a result of the elimination of several positions during the year and reversal of the bonus accrual in the fourth quarter, lower spend on the ASCEND trial, a reduction in patient treatment costs and clinical research organization (“CRO”) expenses associated with our Phase 2a proof-of-concept BOLSTER trial and lower spend on chemistry, manufacturing and controls (“CMC”) partially offset by an increase in expenses associated with our Phase 2a glioblastoma multiforme (“GBM”) proof-of-concept study.
- General and administrative expenses were approximately \$10.4 million for the year ended December 31, 2025, compared to \$12.1 for the year ended December 31, 2024, representing a decrease of approximately \$1.6 million or 13.6%. This was primarily due to a reversal of the bonus accrual in the fourth quarter, one-off settlement costs in the prior year in addition to lower spending on consulting in the current year partially offset by a credit loss allowance, and impairment of a non-financial asset.

Historically, to minimize our use of cash, we have used a variety of equity instruments as compensation to employees, consultants, directors and other service providers. The use of these equity instruments has resulted in non-cash charges to the results of operations, which has been significant in the past.

Other Income

Total other income was \$0.7 million for the year ended December 31, 2025, compared to \$1.6 million for the year ended December 31, 2024, representing a decrease of approximately \$1.0 million or 59.3%. This was primarily due to a reduction in investment income from cash, cash equivalents and marketable securities in the current year as a result of lower investment balances.

Income Tax Benefit

In January 2025, we received final approval from the New Jersey Economic Development Authority (“NJEDA”) under the Technology Business Tax Certificate Transfer Program (the “Program”) to sell a percentage of our NJ NOLs, which were subsequently sold to a qualifying and approved buyer pursuant to the Program for net proceeds of \$0.9 million. The \$1.0 million of our NJ NOL tax benefits have been recorded as a benefit from income taxes and the loss on sale of \$0.1 million recorded in other income (expense).

In March 2024, we received final approval from the NJEDA under the Program to sell a percentage of our NJ NOLs, which were subsequently sold to a qualifying and approved buyer pursuant to the Program for net proceeds of \$0.7 million. The \$0.8 million of our NJ NOL tax benefits have been recorded as a benefit from income taxes and the loss on sale of \$0.1 million recorded in other income (expense).

Analysis of Liquidity and Capital Resources

At December 31, 2025, we had cash and cash equivalents of approximately \$16.0 million, working capital of approximately \$14.6 million, and stockholders’ equity of approximately \$14.9 million.

During the year ended December 31, 2025, we met our immediate cash requirements through existing cash balances. Additionally, we used equity and equity-linked instruments to pay for services and compensation.

Net cash provided by or (used in) operating, investing and financing activities were as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Net cash used in operating activities	\$ (15,949)	\$ (19,356)
Net cash provided by investing activities	15,086	13,233
Net cash provided by (used in) financing activities	599	(206)

Operating Activities

Our cash used in operating activities during the year ended December 31, 2025 totaled approximately \$15.9 million, comprising (i) our net loss of \$16.6 million, as adjusted for non-cash income and expenses totaling \$1.9 million (which includes adjustments for equity-based compensation, depreciation and amortization, impairment of a non-financial asset, amortization/accretion of marketable securities and credit loss allowance), and (ii) changes in operating assets and liabilities using approximately \$1.3 million.

Our cash used in operating activities during the year ended December 31, 2024 totaled approximately \$19.4 million, comprising (i) our net loss of \$20.0 million, as adjusted for non-cash income and expenses totaling \$1.5 million (which includes adjustments for equity-based compensation, depreciation and amortization, loss from equity method investment, and amortization/accretion of marketable securities), and (ii) changes in operating assets and liabilities using approximately \$0.9 million.

Investing Activities

Our cash provided by investing activities during the year ended December 31, 2025 totaled approximately \$15.1 million and was primarily due to net sales of marketable securities (net of purchases of marketable securities).

Our cash provided by investing activities during the year ended December 31, 2024 totaled approximately \$13.2 million and was primarily due to net sales of marketable securities (net of purchases of marketable securities) partially offset by an investment of \$0.1 million in Impilo.

Financing Activities

Our cash provided by financing activities during the year ended December 31, 2025 totaled \$0.6 million in proceeds primarily from the issuance of shares of \$0.8 million through our ATM Agreement (as defined below) partially offset by tax withholding-related payments on net share settlement equity awards to employees of \$0.3 million.

Our cash used in financing activities during the year ended December 31, 2024 totaled \$0.2 million, consisting primarily of tax withholding-related payments on net share settlement equity awards to employees.

Liquidity and Capital Requirements Outlook

As of December 31, 2025, we had cash and cash equivalents of approximately \$16.0 million. We will need to raise additional capital to fund our planned future operations. However, we cannot guarantee that we will be able to obtain sufficient additional funding or that if we do obtain additional funding, that such funding will be obtainable on terms satisfactory to us.

Based on our current business plan and existing capital resources, management has concluded that there is substantial doubt regarding our ability to continue as a going concern for a period of twelve months from the date of issuance of the accompanying consolidated financial statements. The accompanying financial statements have been prepared on a going concern basis and do not include any adjustments to the carrying amounts and classification of assets and liabilities that may be necessary if we were unable to continue as a going concern.

To meet our short and long-term liquidity needs, we expect to use existing cash balances and a variety of other means. Other sources of liquidity could include additional potential issuances of debt or equity securities in public or private financings, partnerships and/or collaborations and/or sale of assets. Our history of operating losses and liquidity challenges may make it difficult for us to raise capital on acceptable terms or at all. The demand for the equity and debt of pharmaceutical companies like ours is dependent upon many factors, including the general state of the financial markets. During times of extreme market volatility, capital may not be available on favorable terms, if at all. Our inability to obtain such additional capital could materially and adversely affect our business operations. We will also continue to seek, as appropriate, grants for scientific and clinical studies from various governmental agencies and foundations, and other sources of non-dilutive funding. As discussed above under recent developments, in January 2026, we entered into the Term Sheet with Kuva for the proposed acquisition of us by Kuva. However, there can be no assurance that the Purchase Agreement will be entered into and the Offer and the Merger will be consummated. Refer to Item 1A. "Risk Factors" for a summary of risks related to the proposed transaction. If the proposed acquisition does not occur, we may pursue other strategic alternatives. Our future capital requirements are difficult to forecast and will depend on many factors, including the timing and nature of the proposed acquisition by Kuva, any other strategic transactions that we undertake and our ability to establish and maintain collaboration partnerships, in-license/out-license or other similar arrangements and the financial terms of such agreements.

On June 4, 2021, we entered into the ATM Agreement with H.C. Wainwright & Co., LLC as sales agent, in connection with an “at the market offering” under which we from time to time may offer and sell shares of our common stock having an aggregate offering price of up to \$50.0 million. As of the date of this filing and so long as our public float remains below \$75.0 million, we are subject to limitations pursuant to General Instruction I.B.6 of Form S-3 (the “Baby Shelf Limitation”), which limits the amount we can offer to up to one-third of our public float during any trailing 12-month period. Subsequent to the filing of a prospectus supplement to our Registration Statement on Form S-3 (File No. 333-279034) relating to the at the market offering on August 21, 2024, the aggregate market value of our outstanding common stock held by non-affiliates was approximately \$29.6 million. Pursuant to the Baby Shelf Limitation, since the aggregate market value of our outstanding common stock held by non-affiliates was below \$75.0 million at the time of such prospectus supplement filing, the aggregate amount of securities that we are permitted to offer and sell pursuant to the ATM Agreement as of the date of this Annual Report on Form 10-K, is \$9,855,890, which amount is equal to one-third of the aggregate market value of our common stock held by non-affiliates as of August 20, 2024. If our public float exceeds \$75.0 million on a future measurement date, the Company will no longer be subject to the Baby Shelf Limitation. During the twelve months ended December 31, 2025, the Company issued 262,765 shares of common stock under the ATM Agreement for net proceeds of \$784,761. Since inception through December 31, 2025, the Company has issued 330,938 shares of common stock under the ATM Agreement for net proceeds of \$1,065,608.

While we continue to seek capital through a number of means, there can be no assurance that additional financing will be available on acceptable terms, if at all, and our negotiating position in capital generating efforts may worsen as existing resources are used. Additional equity financing may be dilutive to our stockholders; debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate as a business; our stock price may not reach levels necessary to induce option or warrant exercises; and asset sales may not be possible on terms we consider acceptable. If we are unable to access capital necessary to meet our long-term liquidity needs, we may have to delay the expansion of our business or raise funds on terms that we currently consider unfavorable.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and judgments that affect the amounts reported in the financial statements. We evaluate our estimates and assumptions on an ongoing basis. We base our estimates on historical experience and other assumptions believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could differ from these estimates.

An accounting policy is considered to be critical if it is important to our financial condition and results of operations and if it requires management’s most difficult, subjective and complex judgments in its application. For a summary of all of our significant accounting policies, see Note 2 to our Consolidated Financial Statements.

Share-Based Compensation

We expense all share-based payment awards to employees, directors, and consultants, including grants of stock options, warrants, and restricted stock, over the requisite service period based on the grant date fair value of the awards. For awards with performance-based vesting criteria, we estimate the probability of achievement of the performance criteria and recognize compensation expense related to those awards expected to vest. We determine the fair value of option awards using the Black-Scholes option-pricing model which uses both historical and current market data to estimate fair value. This method incorporates various assumptions such as the risk-free interest rate, expected volatility, expected dividend yield and expected life of the options or warrants. Share-based compensation expense also includes an estimate, which is made at the time of the grant, of the number of awards that are expected to be forfeited. The fair value of our restricted stock and restricted stock units is based on the closing market price of our common stock on the date of grant.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The financial statements and notes thereto required to be filed under this Item are presented commencing on page 74 of this Annual Report.

Lisata Therapeutics, Inc. and Subsidiaries

Table of Contents

Report of Independent Registered Public Accounting Firm (PCAOB ID Number 248)	77
Financial Statements:	
Consolidated Balance Sheets at December 31, 2025 and 2024	78
Consolidated Statements of Operations - Years Ended December 31, 2025 and 2024	79
Consolidated Statements of Comprehensive Loss - Years Ended December 31, 2025 and 2024	80
Consolidated Statements of Equity - Years Ended December 31, 2025 and 2024	81
Consolidated Statements of Cash Flows - Years Ended December 31, 2025 and 2024	82
Notes to Consolidated Financial Statements	79

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Lisata Therapeutics, Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of Lisata Therapeutics, Inc. (a Delaware corporation) and subsidiaries (the “Company”) as of December 31, 2025 and 2024, the related consolidated statements of operations, comprehensive loss, equity, and cash flows for each of the two years in the period ended December 31, 2025, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Going concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has a history of net operating losses and negative cash flows from operating activities and has cash and cash equivalents of approximately \$16 million as of December 31, 2025. These conditions, along with other matters as set forth in Note 1, raise substantial doubt about the Company’s ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated 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

Critical audit matters 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. We determined that there are no critical audit matters.

/s/ GRANT THORNTON LLP

We have served as the Company’s auditor since 2011.

New York, New York
March 12, 2026

LISATA THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)

	December 31, 2025	December 31, 2024
ASSETS		
Current Assets		
Cash and cash equivalents	\$ 15,956	\$ 16,209
Marketable securities	—	15,036
Accounts receivable	—	900
Prepaid and other current assets	1,747	2,433
Total current assets	17,703	34,578
Property and equipment, net	18	72
Acquired license-intangible, net	—	192
Other assets	23	160
Total assets	<u>\$ 17,744</u>	<u>\$ 35,002</u>
LIABILITIES, NON-CONTROLLING INTERESTS AND STOCKHOLDERS' EQUITY		
Liabilities		
Accounts payable	\$ 1,019	\$ 1,284
Accrued liabilities	2,052	4,329
Total current liabilities	3,071	5,613
Other long-term liabilities	72	72
Total liabilities	3,143	5,685
Commitments and Contingencies (Note 14)		
Stockholders' Equity		
Common stock, \$0.001 par value, authorized 500,000,000 shares; issued 8,834,613 and 8,409,582 shares, at December 31, 2025 and December 31, 2024, respectively; and outstanding, 8,833,875 and 8,408,844 shares, at December 31, 2025 and December 31, 2024, respectively	9	8
Additional paid-in capital	580,243	578,418
Treasury stock, at cost; 738 shares at December 31, 2025 and December 31, 2024 respectively	(708)	(708)
Accumulated deficit	(564,652)	(548,066)
Accumulated other comprehensive loss	(37)	(81)
Total Lisata Therapeutics, Inc. stockholders' equity	14,855	29,571
Non-controlling interests	(254)	(254)
Total equity	14,601	29,317
Total liabilities, non-controlling interests and stockholders' equity	<u>\$ 17,744</u>	<u>\$ 35,002</u>

See accompanying notes to consolidated financial statements.

LISATA THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

	Year Ended December 31,	
	2025	2024
Revenue	\$ 170	\$ 1,000
Operating Expenses:		
Research and development	7,949	11,334
General and administrative	10,430	12,075
Operating expenses	18,379	23,409
Operating loss	(18,209)	(22,409)
Other income (expense):		
Investment income, net	806	1,883
Other expense, net	(145)	(257)
Total other income	661	1,626
Net loss before benefit from income taxes and noncontrolling interests	(17,548)	(20,783)
Benefit from income taxes	(962)	(798)
Net loss	\$ (16,586)	\$ (19,985)
Less - net income (loss) attributable to noncontrolling interests	—	—
Net loss attributable to Lisata Therapeutics, Inc. common stockholders	<u>\$ (16,586)</u>	<u>\$ (19,985)</u>
Basic and diluted loss per share:		
Lisata Therapeutics, Inc. common stockholders	\$ (1.91)	\$ (2.40)
Weighted average common shares outstanding:		
Basic and diluted shares	8,687	8,329

See accompanying notes to consolidated financial statements.

LISATA THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)

	Year Ended December 31,	
	2025	2024
Net loss	\$ (16,586)	\$ (19,985)
Other comprehensive income (loss):		
Available for sale securities - net unrealized gain	4	1
Cumulative translation adjustment arising during the period	40	(40)
Total other comprehensive income (loss)	44	(39)
Comprehensive loss	(16,542)	(20,024)
Comprehensive income (loss) attributable to noncontrolling interests	—	—
Comprehensive loss attributable to Lisata Therapeutics, Inc. common stockholders	<u>\$ (16,542)</u>	<u>\$ (20,024)</u>

See accompanying notes to consolidated financial statements.

LISATA THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EQUITY
(In thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Treasury Stock	Total Lisata Therapeutics, Inc. Stockholders' Equity	Non- Controlling Interest in Subsidiary	Total Equity
	Shares	Amount							
Balance at December 31, 2023	8,151	\$ 8	\$ 576,971	\$ (42)	\$ (528,081)	\$ (708)	\$ 48,148	\$ (254)	\$ 47,894
Net loss	—	—	—	—	(19,985)	—	(19,985)	—	(19,985)
Share-based compensation	218	—	1,379	—	—	—	1,379	—	1,379
Net proceeds from issuance of common stock	28	—	68	—	—	—	68	—	68
Proceeds from option exercises	13	—	—	—	—	—	—	—	—
Unrealized gain on marketable securities	—	—	—	1	—	—	1	—	1
Foreign currency translation adjustment	—	—	—	(40)	—	—	(40)	—	(40)
Balance at December 31, 2024	8,410	\$ 8	\$ 578,418	\$ (81)	\$ (548,066)	\$ (708)	\$ 29,571	\$ (254)	\$ 29,317
Net loss	—	—	—	—	(16,586)	—	(16,586)	—	(16,586)
Share-based compensation	129	—	974	—	—	—	974	—	974
Net proceeds from issuance of common stock	292	1	843	—	—	—	844	—	844
Proceeds from option exercises	4	—	8	—	—	—	8	—	8
Unrealized gain on marketable securities	—	—	—	4	—	—	4	—	4
Foreign currency translation adjustment	—	—	—	40	—	—	40	—	40
Balance at December 31, 2025	8,835	\$ 9	\$ 580,243	\$ (37)	\$ (564,652)	\$ (708)	\$ 14,855	\$ (254)	\$ 14,601

See accompanying notes to consolidated financial statements.

LISATA THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2025	2024
Cash flows from operating activities:		
Net loss	\$ (16,586)	\$ (19,985)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	1,226	1,653
Depreciation and amortization	146	174
Loss from equity method investment	—	130
Impairment of non-financial asset	127	—
Amortization/accretion on marketable securities	(75)	(455)
Allowance for credit losses	500	—
Changes in operating assets and liabilities:		
Accounts receivable	401	(900)
Prepaid and other current assets	742	852
Other assets	140	170
Accounts payable, accrued liabilities and other liabilities	(2,570)	(995)
Net cash used in operating activities	(15,949)	(19,356)
Cash flows from investing activities:		
Purchase of marketable securities	(9,180)	(55,688)
Sales of marketable securities	24,294	69,051
Investment in Impilo Therapeutics	—	(130)
Purchases of property and equipment	(28)	—
Net cash provided by investing activities	15,086	13,233
Cash flows from financing activities:		
Proceeds from exercise of options	8	—
Tax withholding payments on net share settlement equity awards	(253)	(274)
Net proceeds from issuance of common stock	844	68
Net cash provided by (used in) financing activities	599	(206)
Effect of exchange rate changes on cash	11	(55)
Net decrease in cash and cash equivalents	(253)	(6,384)
Cash and cash equivalents at beginning of year	16,209	22,593
Cash and cash equivalents at end of year	\$ 15,956	\$ 16,209

See accompanying notes to consolidated financial statements.

LISATA THERAPEUTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 – Description of Business

Overview

Lisata Therapeutics, Inc. (together with its subsidiaries, the “Company”) is a clinical-stage pharmaceutical company dedicated to the discovery, development, and commercialization of innovative therapies for the treatment of solid tumors and other serious diseases. The Company's investigational product, certepetide (formerly known as LSTA1 or CEND-1), is designed to activate a novel uptake pathway (the C-end rule active transport mechanism) that allows co-administered or tethered (i.e., molecularly bound) anti-cancer drugs to target and penetrate solid tumors more effectively. Certepetide actuates this active transport system in a tumor-specific manner, resulting in systemically co-administered anti-cancer drugs more efficiently penetrating and accumulating in the tumor, while normal tissues are expected to remain unaffected. Certepetide has also been shown to modify the tumor microenvironment (“TME”) by reducing T-regulatory cells and augmenting cytotoxic T cells, thereby making tumors more susceptible to immunotherapies while also inhibiting the metastatic cascade (i.e., the spread of cancer to other parts of the body). The Company, its collaborators and other researchers have amassed and continue to amass significant non-clinical data demonstrating enhanced delivery of a range of existing and emerging anti-cancer therapies, including chemotherapeutics, immunotherapies, and RNA-based therapeutics. In addition, certain preclinical data using certepetide in combination with antibody drug conjugates (ADCs) has been generated as part of the Company’s research collaboration with Catalent. These data were presented recently at a scientific meeting during the fourth quarter of 2025. To date, certepetide has also demonstrated favorable safety, tolerability and activity in completed and ongoing clinical trials designed to enhance delivery of standard-of-care chemotherapy, with and without added immunotherapy for pancreatic cancer. Certepetide is or has been the subject of several Phase 2 clinical studies globally in a variety of solid tumor types, including metastatic pancreatic ductal adenocarcinoma (mPDAC), cholangiocarcinoma, appendiceal cancer, colon cancer and glioblastoma multiforme in combination with a variety of anti-cancer regimens.

The Company's leadership team has amassed many decades of collective biopharmaceutical and pharmaceutical product development experience across a variety of therapeutic categories and at all stages of development from preclinical through to product registration and launch. The Company's goal is to develop and commercialize products that address important unmet medical needs.

Liquidity and Capital Resources

The Company has a history of net operating losses and negative cash flows from its operating activities, and has cash and cash equivalents of approximately \$16.0 million as of December 31, 2025. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant revenues from its products currently in development. To manage capital for operating needs in the short-term, as previously disclosed, the Company has delayed commencement of certain readiness activities for its planned Phase 3 study in metastatic pancreatic ductal adenocarcinoma (mPDAC), particularly those related to chemistry, manufacturing and controls (“CMC”). The Company’s ongoing trials continue to progress as planned.

The Company’s continued operations are dependent on its ability to raise additional funding. Based on its current business plan and current capital resources, combined with the need to raise additional funding and the uncertainty regarding the availability of such additional funding, management has concluded that there is substantial doubt regarding the Company’s ability to continue as a going concern for a period of twelve months after the date these consolidated financial statements are issued. Management's plans to alleviate the conditions that raise substantial doubt regarding the Company’s ability to continue as a going concern include obtaining additional funding through equity or debt offerings and/or pursuing collaboration or licensing arrangements. However, additional funding may not be available on terms acceptable to the Company or at all. The Company may also continue to reduce current spending requirements where necessary.

If, for any reason, the Company utilizes its capital resources more quickly than anticipated or is unable to obtain additional funding on a timely basis, it may be required to revise its business plan and strategy. This may result in the Company significantly curtailing, delaying or discontinuing its research and development programs. As a result, the Company’s business, financial condition, and results of operations could be materially affected. The accompanying consolidated financial statements do not include any adjustments to the carrying amounts and classification of assets and liabilities that may be necessary if the Company were unable to continue as a going concern.

Proposed Acquisition by Kuva Labs Inc.

On March 6, 2026, the Company entered into an Agreement and Plan of Merger (the “Merger Agreement”) with Kuva Labs Inc. (“Kuva”), and Kuva Acquisition Corp., a wholly owned subsidiary of Kuva (“Purchaser”). Pursuant to the Merger Agreement, and upon the terms and subject to the conditions thereof, Purchaser will commence a tender offer (the “Offer”) to purchase all of the issued and outstanding shares of common stock, par value \$0.001 per share (the “Common Shares”), of the Company in exchange for (i) \$5.00 per Common Share, net to the seller in cash, without interest, but subject to any applicable withholding of taxes (the “Closing Amount”) plus (ii) one non-tradeable contingent value right (each, a “CVR”), which represents the contractual right to receive a contingent cash payment of \$1.00 per CVR if a New Drug Application or similar registration is filed or formally accepted for review by the FDA or any governmental authority in any jurisdiction with respect to any pharmaceutical product that contains or incorporates the product candidate referred to as of the date of the Merger Agreement as certepetide, alone or in combination with one or more other therapeutically active ingredients, including all formulations, dosages, or modes of delivery, for any indication or patient population prior to the earlier of (a) 11:59 p.m. New York City Time on the seventh (7th) anniversary of the Closing Date (as defined in the Merger Agreement), and (b) termination of the CVR Agreement (the “Milestone”), in accordance with the terms and subject to the conditions of a contingent value rights agreement (the “CVR Agreement”) to be entered into with a rights agent selected by Kuva and reasonably acceptable to the Company (the Closing Amount plus one CVR, collectively, the “Offer Price”). If certain conditions are satisfied and the Offer is consummated, Kuva would acquire any remaining Shares for the Offer Price by a merger of Purchaser with and into the Company (the “Merger”). Upon completion of these transactions, the Company would no longer be a publicly traded company and the listing of its common stock on Nasdaq will terminate.

Under the Merger Agreement, the Offer and the Merger are subject to customary closing conditions for a transaction of this nature. Kuva will be required to close on the Offer so long as there shall be validly tendered a number of shares that represents (and will represent immediately following the consummation of the Offer) at least a majority of the aggregate voting power of all shares then outstanding. There can be no assurance that the Offer and the Merger will be consummated.

The foregoing description of the Merger Agreement is only a summary of certain material provisions thereof, does not purport to be complete. The full text of the Merger Agreement is filed as Exhibit 2.1 to this Annual Report on Form 10-K.

Basis of Presentation

The accompanying consolidated financial statements and accompanying notes have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”).

Segment Information

The Company operates as one operating segment, the research and development of its investigational drug product. The Company's Chief Operating Decision Maker (“CODM”) is its Chief Executive Officer, who manages the business on a consolidated basis.

Note 2 – Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements. Estimates also affect the reported amounts of expenses during the reporting period. The Company bases its estimates on historical experience and other assumptions believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. The Company makes critical estimates and assumptions in determining stock-based awards values. Accordingly, actual results could differ from those estimates and assumptions.

Recently issued accounting pronouncements not yet adopted

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*, requiring public entities to disclose additional information about specific expense categories in the notes to the financial statements on an interim and annual basis. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and for interim periods beginning

after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2024-03.

Recently adopted accounting pronouncements

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, requiring public entities to disclose information about their reportable segments' significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements in ASC 280 on an interim and annual basis. The Company adopted ASU 2023-07 during the year ended December 31, 2024. These amendments were effective for the Company in 2024 and retrospectively to all prior periods using the significant segment expense categories identified. The impact of the adoption of the amendments in this update was not material to the Company's consolidated financial position and results of operations, as the requirements impact only segment reporting disclosures in the footnotes to the Company's consolidated financial statements. See Note 12 Segment Information in the accompanying notes to the consolidated financial statements for further detail.

In December 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which requires public entities, on an annual basis, to provide disclosure of specific categories in the rate reconciliation, as well as disclosure of income taxes paid disaggregated by jurisdiction. The Company adopted ASU 2023-09 during the year ended December 31, 2025. The adoption of this standard did not have a material impact on our consolidated financial statements and related disclosures.

Principles of Consolidation

The Consolidated Financial Statements include the accounts of Lisata Therapeutics, Inc. and its wholly owned and majority owned subsidiaries and affiliates. All intercompany activities have been eliminated in consolidation.

Foreign Currency Remeasurement

The Company's reporting currency is the U.S. Dollar. The functional currency of Lisata Therapeutics Australia Pty Ltd., which is a foreign subsidiary of the Company, is the Australian Dollar. The assets and liabilities of Lisata Therapeutics Australia Pty Ltd. are translated into U.S. Dollars at the exchange rates in effect at each balance sheet date, and the results of operations are translated using the average exchange rates prevailing throughout the reporting period. Adjustments resulting from translating foreign functional currency financial statements into U.S. Dollars are included in the foreign currency translation adjustment, a component of accumulated other comprehensive income (loss) in stockholders' equity.

Cash and Cash Equivalents

Cash and cash equivalents include short-term, highly liquid, investments with maturities of ninety days or less when purchased.

Concentration of Risks

The Company is subject to credit risk from its portfolio of cash, cash equivalents, accounts receivable and marketable securities. Under its investment policy, the Company limits amounts invested in such securities by credit rating, maturity, industry group, investment type and issuer, except for securities issued by the U.S. government, thereby reducing credit risk exposure. Cash is held at major banks in the United States and may exceed federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. The goals of the Company's investment policy, in order of priority, are as follows: safety and preservation of principal and diversification of risk, liquidity of investments sufficient to meet cash flow requirements, and a competitive after-tax rate of return. The Company had \$— million and \$0.9 million in accounts receivable as of December 31, 2025 and 2024, respectively. The Company has no significant off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts, or other hedging arrangements.

Accounts Receivable

Accounts receivable is stated at historical cost, less allowance for credit losses. The Company records an expense based on a forward-looking current expected credit loss model to maintain its allowance for credit losses. When determining its allowance for trade accounts receivable, the Company considers the probability of recoverability of accounts receivable based on experience, taking into account current collection trends and general economic factors, including bankruptcy rates. The Company also considers future economic trends to estimate expected credit losses over the lifetime of the asset. Credit risks are assessed based on historical write-offs, net of recoveries, as well as an analysis of the aged accounts receivable balances with allowances generally increasing as the receivable ages. Accounts receivable may be fully reserved for when specific collection

issues are known to exist, such as pending bankruptcies. Account balances are written off against the allowance when it is determined that the receivable will not be recovered. The Company increased its allowance for credit losses during the quarter ended December 31, 2025 by \$0.5 million. As of December 31, 2025, the associated accounts receivable was uncollectible and written off (See Note 17). As of December 31, 2025 and 2024, there were no allowance for credit losses.

Marketable Securities

The Company determines the appropriate classification of its marketable securities at the time of purchase and reevaluates such designation at each balance sheet date. All of the Company's marketable securities are considered as available-for-sale and carried at estimated fair values and reported in cash equivalents and marketable securities. Unrealized gains and losses on available-for-sale securities, that are not the result of credit losses, are excluded from net income and reported in accumulated other comprehensive income (loss) as a separate component of stockholders' equity. Other income (expense), net, includes interest, dividends, amortization of purchase premiums and discounts, realized gains and losses on sales of securities and credit losses recognized through an allowance for credit losses, if any. The cost of securities sold is based on the specific identification method. The Company regularly reviews all of its investments for other-than-temporary declines in fair value. The Company's review includes the consideration of the cause of the impairment, including the creditworthiness of the security issuers, the number of securities in an unrealized loss position, the severity and duration of the unrealized losses, whether the Company has the intent to sell the securities and whether it is more likely than not that it will be required to sell the securities before the recovery of their amortized cost basis. When the Company determines that the decline in fair value of an investment is below its accounting basis and this decline is other-than-temporary, it reduces the carrying value of the security it holds and records a loss for the amount of such decline.

Property and Equipment

The cost of property and equipment is depreciated over the estimated useful lives of the related assets. Depreciation is computed on the straight-line method. Repairs and maintenance expenditures that do not extend original asset lives are charged to expense as incurred. The estimated useful lives of property and equipment are as follows:

Furniture and fixtures	10 years
Computer equipment	3 years
Software	3 years
Leasehold improvements	Shorter of useful life or lease term

Long-lived Assets

Long-lived assets consist of property and equipment. The assets are amortized on a straight-line basis over their respective useful lives. The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset exceeds the fair value of the asset. If other events or changes in circumstances indicate that the carrying amount of an asset that the Company expects to hold and use may not be recoverable, the Company will estimate the undiscounted future cash flows expected to result from the use of the asset and/or its eventual disposition, and recognize an impairment loss, if any. The impairment loss, if determined to be necessary, would be measured as the amount by which the carrying amount of the assets exceeds the fair value of the assets.

Share-Based Compensation

The Company expenses all share-based payment awards to employees, directors, and consultants, including grants of stock options, warrants, and restricted stock, over the requisite service period based on the grant date fair value of the awards. For awards with performance-based vesting criteria, the Company estimates the probability of achievement of the performance criteria and recognizes compensation expense related to those awards expected to vest. The Company determines the fair value of option awards using the Black-Scholes option-pricing model which uses both historical and current market data to estimate the fair value. This method incorporates various assumptions such as the risk-free interest rate, expected volatility, expected dividend yield and expected life of the options or warrants. Share-based compensation expense also includes an estimate, which is made at the time of the grant, of the number of awards that are expected to be forfeited. The fair value of the Company's restricted stock and restricted stock units is based on the closing market price of the Company's common stock on the date of grant.

Loss Per Share

Basic loss per share is based on the weighted effect of all shares of common stock issued and outstanding and is calculated by dividing net loss attributable to common stockholders by the weighted average shares outstanding during the period. Diluted loss per share is calculated by dividing net loss attributable to common stockholders by the weighted average number of shares

of common stock used in the basic loss per share calculation plus the number of shares of common stock that would be issued assuming conversion of all potentially dilutive securities outstanding. Diluted loss per share is not presented as such potentially dilutive securities are anti-dilutive to losses incurred in all periods presented.

Treasury Stock

Treasury stock purchases are accounted for under the cost method whereby the entire cost of the acquired stock is recorded as treasury stock. Gains or losses on the subsequent reissuance of shares are credited or charged to additional paid in capital.

Research and Development Costs

Research and development (“R&D”) expenses include salaries, benefits, and other headcount related costs, clinical trial and related clinical manufacturing costs, contract and other outside service fees including sponsored research agreements, and facilities and overhead costs. The Company expenses the costs associated with research and development activities when incurred.

To further drive the Company’s initiatives, the Company will continue targeting key governmental agencies and not-for-profit organizations to contribute funds for the Company’s research and development programs. The Company accounts for such grants as a deduction to the related expense in research and development operating expenses when earned.

In-process Research and Development Expense

Upfront payments that relate to the acquisition of a new drug compound, as well as pre-commercial milestone payments, are immediately expensed as IPR&D in the period in which they are incurred, provided that the new drug compound did not also include processes or activities that would constitute a “business” as defined under U.S. GAAP, the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no established alternative future use. The Company accounts for contingent consideration payable upon achievement of certain regulatory, development or sales milestones in such asset acquisitions when the underlying contingency is probable and estimable. Milestone payments made to third parties subsequent to regulatory approval will be capitalized as intangible assets and amortized over the estimated remaining useful life of the related product.

Intangible Asset

The Company’s intangible asset consists of a single asset, a license agreement with Qilu Pharmaceutical, Co., Ltd. (“Qilu”) acquired in the Company’s acquisition of Cend Therapeutics, Inc (the “Cend Merger”), with a value of \$0.4 million. The intangible asset is stated at fair value and is amortized using the straight-line method over its estimated useful life of 5 years. Amortization expense was \$65 thousand and \$71 thousand for the years ended December 31, 2025 and December 31, 2024, respectively. The intangible asset is reviewed for potential impairment when events or circumstances indicate that carrying amounts may not be recoverable. As of December 31, 2025, the Company determined that the carrying amount of the asset was not recoverable and recorded an intangible asset impairment charge of \$0.1 million in general and administrative expenses in the Consolidated Statements of Operations.

Revenue Recognition

The Company evaluates license and collaboration arrangements to determine whether units of account within the arrangement exhibit the characteristics of a vendor and customer relationship. For arrangements and units of account where a customer relationship exists, the Company applies the revenue recognition guidance. The Company recognizes revenue upon the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with customers the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies the performance obligations. At contract inception, the Company assesses the goods or services promised within each contract and assesses whether each promised good or service is distinct and determines those that are performance obligations. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Taxes imposed by governmental authorities on the Company’s revenue, such as sales taxes and withholding taxes, are excluded from net revenue.

If a license to the Company’s intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. If licenses are bundled with other performance obligations, the Company would utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over

time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company recognized revenue of \$0.2 million and \$1.0 million for the years ended December 31, 2025 and 2024, respectively.

Milestones

At the inception of each arrangement that includes milestone payments (variable consideration), the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company or the Company's collaboration partner's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and if necessary, adjusts the Company's estimate of the overall transaction price. Any such adjustments are allocated on a cumulative catch-up basis to satisfied and partially satisfied performance obligations, with the consideration allocated to an ongoing performance obligation being recognized over the period of performance. For the years ended December 31, 2025 and 2024 the Company has not recognized revenue related to milestones.

Royalties

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue from any collaborative arrangement.

Note 3 – Available-for-Sale-Securities

The following table is a summary of available-for-sale securities recorded in cash and cash equivalents or marketable securities in the Company's Consolidated Balance Sheets (in thousands):

	December 31, 2025				December 31, 2024			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities	\$ —	\$ —	\$ —	\$ —	\$ 16,025	\$ —	\$ (4)	\$ 16,021
Money market funds	11,640	—	—	11,640	6,614	—	—	6,614
Agency bonds	—	—	—	—	613	—	—	613
Treasury bills	—	—	—	—	1,496	—	—	1,496
Municipal debt securities	—	—	—	—	905	—	—	905
Total	<u>\$ 11,640</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 11,640</u>	<u>\$ 25,653</u>	<u>\$ —</u>	<u>\$ (4)</u>	<u>\$ 25,649</u>

Estimated fair values of available-for-sale securities are generally based on prices obtained from commercial pricing services. The following table summarizes the classification of the available-for-sale securities in the Company's Consolidated Balance Sheets (in thousands):

	December 31, 2025	December 31, 2024
Cash equivalents	\$ 11,640	\$ 10,613
Marketable securities	—	15,036
Total	<u>\$ 11,640</u>	<u>\$ 25,649</u>

The following table summarizes the Company's portfolio of available-for-sale securities by contractual maturity (in thousands):

	December 31, 2025		December 31, 2024	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Less than one year	\$ 11,640	\$ 11,640	\$ 25,653	\$ 25,649
Greater than one year	—	—	—	—
Total	<u>\$ 11,640</u>	<u>\$ 11,640</u>	<u>\$ 25,653</u>	<u>\$ 25,649</u>

Note 4 – Property and Equipment

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

	December 31,	
	2025	2024
Computer equipment	494	589
Leasehold improvements	—	72
Property and equipment, gross	494	661
Accumulated depreciation	(476)	(589)
Property and equipment, net	<u>\$ 18</u>	<u>\$ 72</u>

The Company's results included depreciation expense of approximately \$0.1 million and \$0.1 million for the years ended December 31, 2025 and 2024, respectively.

Note 5 – Income (Loss) Per Share

For the years ended December 31, 2025 and 2024, the Company incurred net losses and therefore no common stock equivalents were utilized in the calculation of diluted loss per share as they are anti-dilutive in the periods presented. At December 31, 2025 and 2024, the Company excluded the following potentially dilutive securities (in thousands):

	December 31,	
	2025	2024
Stock options	1,503	1,441
Warrants	1,277	1,497
Restricted stock units	325	246

Note 6 – Fair Value Measurements

Fair value of financial assets and liabilities that are being measured and reported are defined as the exchange price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the principal market at the measurement date (exit price). The Company is required to classify fair value measurements in one of the following categories:

Level 1 inputs are defined as quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2 inputs are defined as inputs other than quoted prices included within Level 1 that are observable for the assets or liabilities, either directly or indirectly.

Level 3 inputs are defined as unobservable inputs for the assets or liabilities. Financial assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of the fair value of assets and liabilities and their placement within the fair value hierarchy levels.

The Company's financial assets and liabilities that were accounted for at fair value on a recurring basis as of December 31, 2025 and December 31, 2024 were as follows (in thousands):

	December 31, 2025				December 31, 2024			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Cash equivalents	\$ 11,640	\$ —	\$ —	\$ 11,640	\$ 10,613	\$ —	\$ —	\$ 10,613
Marketable securities - available for sale	—	—	—	—	—	15,036	—	15,036
	<u>\$ 11,640</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 11,640</u>	<u>\$ 10,613</u>	<u>\$ 15,036</u>	<u>\$ —</u>	<u>\$ 25,649</u>

The carrying values of cash, cash equivalents, accounts receivable, accounts payable and accrued expenses approximate fair value at December 31, 2025 and December 31, 2024, due to the short maturity nature of these items.

Note 7 – Accrued Liabilities

Accrued liabilities were as follow (in thousands):

	December 31,	
	2025	2024
Salaries, employee benefits and related taxes	\$ 812	\$ 2,640
Operating lease liabilities - current	—	137
Clinical and R&D related liabilities	1,022	1,333
Accounting & tax consulting liabilities	62	55
Other	156	164
	<u>\$ 2,052</u>	<u>\$ 4,329</u>

Note 8 – Operating Leases

The Company had an operating lease for one office which expired in 2025, however, based on prior understanding with the building's management, continue to occupy a portion of office space in the building on a non-committal basis. The Company estimates its incremental borrowing rate at lease commencement to determine the present value of lease payments as the Company's lease did not provide an implicit rate of return. The Company recognized lease expense on a straight-line basis over the lease term. For lease agreements entered into or reassessed after the adoption of ASU No. 2016-02, Leases (Topic 842), the Company elected to account for non-lease components associated with its leases and lease components as a single lease

component. The Company's lease included an option for the Company to extend the lease term and/or sub-lease space in whole or in part for which the Company has not exercised.

Operating lease liabilities and right-of-use assets were recorded in the following captions of the Company's balance sheet as follows (in thousands):

	December 31, 2025	December 31, 2024
Right-of-Use Assets:		
Other assets	\$ —	\$ 138
Total Right-of-Use Asset	\$ —	\$ 138
Operating Lease Liabilities:		
Accrued liabilities	\$ —	\$ 137
Other long-term liabilities	—	—
Total Operating Lease Liabilities	\$ —	\$ 137

As of December 31, 2024, the weighted average remaining lease term for the Company's operating lease was 0.75 years, and the weighted average discount rate for the Company's operating leases was 9.625%.

Operating lease costs were \$0.1 million and \$0.2 million for the years ended December 31, 2025 and 2024, respectively and includes both cash and non-cash expenses for operating leases. The operating lease costs are recognized evenly over the lease term, therefore, the timing of the expense may differ from the timing of actual cash payments. Cash payments and lease costs can differ due to the timing of cash payments relative to the level expense. Operating lease costs are included in research and development and general and administrative expense in the accompanying consolidated statements of operations.

Note 9 – Stockholders' Equity

Equity Plans

The Company has used long-term incentive plans for the purpose of granting equity awards to employees of the Company, including officers, and nonemployees, including consultants and nonemployee members of the Company's board of directors (collectively, the "Participants"). The Participants may receive awards as determined by a committee of independent members of the Company's board of directors or, to the extent authorized by such committee with respect to certain Participants, a duly authorized employee (collectively, the "Committee"). The incentive plan currently used by the Company is the 2018 Equity Incentive Compensation Plan (the "2018 Plan"), as adopted by the stockholders of the Company in (i) June 2018, and subsequently increased by the stockholders of the Company in June 2024 with 600,000 shares authorized for issuance thereunder and 862,135 additional shares authorized for issuance thereunder pursuant to the automatic annual evergreen increase, in (ii) June 2023 with 400,000 shares authorized for issuance thereunder, in (iii) September 2022 with 333,333 shares authorized for issuance thereunder, in (iv) June 2021 with 400,000 shares authorized for issuance thereunder and in (v) June 2020 with 166,667 shares authorized for issuance thereunder, plus any shares awarded under the 2015 Equity Compensation Plan (the "2015 Plan") or the Amended and Restated 2009 Equity Compensation Plan (the "2009 Plan") that are not issued due to their subsequent forfeiture, cancellation, or other settlement thereof. Concurrent with the adoption of the 2018 Plan, no future awards will occur under the 2015 Plan or the 2009 Plan. The awards that may be made under the 2018 Plan include: (a) incentive stock options and nonqualified stock options, (b) shares of restricted stock, (c) restricted stock units, and (d) other kinds of equity-based compensation awards. All stock options under the 2015 Plan and 2009 Plan were granted and the 2018 Plan are granted at the fair market value of the common stock at the grant date. Stock options vest either on the date of grant, ratably over a period determined at time of grant (typically over 3 years) or upon the accomplishment of specified business milestones, and generally expire 2, 3, or 10 years from the grant date depending on the status of the recipient as a nonemployee, employee or director of the Company. As of December 31, 2025 and 2024 there were 463,373 shares and 744,514 shares, respectively available for future grants under the 2018 Plan. No additional awards may be made under the 2015 Plan or the 2009 Plan.

The Company adopted an employee stock purchase plan effective January 1, 2013 and authorized 3,333 shares under the plan (the "2012 ESPP"). The plan has two six-month offering periods per year under which eligible employees may contribute

up to 15% of their compensation toward the purchase of the Company's common stock per offering period (with a \$25,000 fair market value cap per calendar year). The employee's purchase price is equal to (i) 85% of the closing price of a share of the Company's common stock on the enrollment date of such offering period or (ii) 85% of the closing price of a share of the Company's common stock on the Exercise Date of such Offering Period, whichever is lower. In May 2017, the Company's stockholders approved an amendment and restatement to the 2012 ESPP (the "2017 ESPP") in order to effect an increase of authorized shares from 3,333 to 6,667. In June 2018, the Company's stockholders approved an amendment to the 2017 ESPP (the "Amended 2017 ESPP") in order to effect an increase of authorized shares from 6,667 to 33,333. In June 2023, the Company's stockholders approved an amendment to the Amended 2017 ESPP in order to effect an increase of authorized shares from 33,333 to 68,333. In June 2024, the Company's stockholders approved an amendment to the Amended 2017 ESPP in order to effect an increase of authorized shares from 68,333 shares to 113,333 shares.

During the year ended December 31, 2025, 28,484 shares were issued under the Amended 2017 ESPP. At December 31, 2025 and 2024, the Company had 14,637 shares and 43,121 shares, respectively of the Company's common stock available for future grant in connection with this plan.

Equity Issuances

At The Market Offering Agreement

On June 4, 2021, the Company entered into an At The Market Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC, as sales agent, in connection with an "at the market offering" under which the Company from time to time may offer and sell shares of its common stock, having an aggregate offering price of up to \$50.0 million. As of the date of this filing and so long as the Company's public float remains below \$75.0 million, the Company is subject to limitations pursuant to General Instruction I.B.6 of Form S-3 (the "Baby Shelf Limitation"), which limits the amount the Company can offer to up to one-third of its public float during any trailing 12-month period. Subsequent to the filing of a prospectus supplement to the Company's Registration Statement on Form S-3 (File No. 333-279034) relating to the at the market offering on August 21, 2024, the aggregate market value of its outstanding common stock held by non-affiliates was approximately \$29.6 million. Pursuant to the Baby Shelf Limitation, since the aggregate market value of the Company's outstanding common stock held by non-affiliates was below \$75.0 million at the time of such prospectus supplement filing, the aggregate amount of securities that the Company is permitted to offer and sell pursuant to the ATM Agreement as of the date of this Annual Report on Form 10-K, is \$9,855,890, which is equal to one-third of the aggregate market value of our common stock held by non-affiliates as of August 20, 2024. If the Company's public float exceeds \$75.0 million on a future measurement date, it will no longer be subject to the Baby Shelf Limitation. During the year ended December 31, 2025, the Company issued 262,765 shares of common stock under the ATM Agreement for net proceeds of \$784,761. Since inception through December 31, 2025, the Company has issued 330,938 shares of common stock under the ATM Agreement for net proceeds of \$1,065,608.

Stock Options and Warrants

The following table summarizes the activity for stock options and warrants for the year ended December 31, 2025:

	Stock Options				Warrants			
	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (In Thousands)	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (In Thousands)
Outstanding at December 31, 2024	1,440,535	\$ 8.82	5.46	\$ 157.0	1,496,744	\$ 40.52	1.29	\$ 7.5
Changes during the Year:								
Granted	111,400	\$ 3.80			—	—		
Exercised	(4,329)	\$ 1.88			—	—		
Forfeited	(17,930)	\$ 3.53			131,628	43.50		
Expired	(26,795)	\$ 141.14			88,154	32.09		
Outstanding at December 31, 2025	1,502,881	\$ 6.17	4.77	\$ 24.6	1,276,962	\$ 40.80	0.29	\$ —
Vested at December 31, 2025 or expected to vest in the future	1,497,282	\$ 6.18	4.76	\$ 24.6	1,276,962	\$ 40.80	0.29	\$ —
Exercisable at December 31, 2025	1,337,823	\$ 6.51	4.33	\$ 24.6	1,276,962	\$ 40.80	0.29	\$ —

Restricted Stock

During the years ended December 31, 2025 and 2024, the Company issued restricted stock for services as follows (\$ in thousands, except share data):

	2025	2024
Number of restricted stock issued	215,550	203,800
Value of restricted stock issued	\$ 819.1	\$ 627.7

The weighted average estimated fair value of restricted stock issued for services in the years ended December 31, 2025 and 2024 was \$3.80 and \$3.08 per share, respectively. The fair value of the restricted stock was determined using the Company's closing stock price on the date of issuance. The vesting terms of restricted stock issuances are generally between one year and four years.

The following is a summary of the changes in non-vested restricted stock for the year ended December 31, 2025:

	Restricted Stock Shares	Weighted Average Grant-Date Fair Value
Non-vested at December 31, 2024	228,428	\$ 3.67
Changes during the Year:		
Granted	215,550	\$ 3.80
Vested	(161,492)	\$ 4.20
Forfeited	(17,450)	\$ 3.50
Non-vested at December 31, 2025	265,036	\$ 3.46

Restricted Stock Units

During the years ended December 31, 2025 and 2024, the Company issued restricted stock units for services as follows (\$ in thousands, except share data):

	2025	2024
Number of restricted stock units issued	78,945	205,300
Value of restricted stock units issued	\$ 300.0	\$ 632.3

The weighted average estimated fair value of restricted stock units issued for services in the years ended December 31, 2025 and 2024 was \$3.80 and \$3.08 per share, respectively. The fair value of the restricted stock units was determined using the Company's closing stock price on the date of issuance. The vesting terms of restricted stock unit issuances are generally one year, or upon the achievement of performance-based milestones.

The following is a summary of the changes in non-vested restricted stock units for the year ended December 31, 2025:

	Restricted Stock Units	Weighted Average Grant-Date Fair Value
Non-vested at December 31, 2024	103,800	\$ 3.28
Changes during the Year:		
Granted	78,945	\$ 3.80
Vested	(103,800)	\$ 3.28
Forfeited	—	\$ —
Non-vested at December 31, 2025	78,945	\$ 3.80

Note 10 – Share-Based Compensation

Share-Based Compensation

The Company utilizes share-based compensation in the form of stock options, restricted stock, restricted stock units and warrants. The following table summarizes the components of share-based compensation expense for the years ended December 31, 2025 and 2024 (\$ in thousands):

	Year Ended December 31,	
	2025	2024
Research and development	\$ 228	\$ 270
General and administrative	998	1,383
Total share-based compensation expense	\$ 1,226	\$ 1,653

Total compensation cost related to unvested awards not yet recognized and the weighted-average periods over which the awards are expected to be recognized at December 31, 2025 were as follows (\$ in thousands):

	Stock Options	Restricted Stock Units	Warrants	Restricted Stock
Unrecognized compensation cost	\$ 216	\$ 7	\$ —	\$ 527
Expected weighted-average period in years of compensation cost to be recognized	1.65	0.02	0.00	1.74

Total fair value of shares vested and the weighted average estimated fair values of shares granted for the years ended December 31, 2025 and 2024 were as follows (\$ in thousands):

	Stock Options		Warrants	
	Year Ended December 31,		Year Ended December 31,	
	2025	2024	2025	2024
Total fair value of shares vested	\$ 267	\$ 204	\$ 150	\$ —
Weighted average estimated fair value of shares granted	2.60	2.15	—	1.99

Valuation Assumptions

The fair value of stock options and warrants at the date of grant was estimated using the Black-Scholes option pricing model. The expected volatility is based upon historical volatility of the Company's stock. The expected term for the options is based upon observation of actual time elapsed between date of grant and exercise of options for all employees. The expected term for the warrants is based upon the contractual term of the warrants.

The range of assumptions made in calculating the fair values of stock options was as follows:

	Stock Options	
	Year Ended December 31,	
	2025	2024
Expected term - minimum (in years)	6.3	6.0
Expected term - maximum (in years)	6.3	6.3
Expected volatility - minimum	73%	73%
Expected volatility - maximum	73%	77%
Weighted average volatility	73%	77%
Expected dividend yield	—	—
Risk-free interest rate - minimum	4.51%	3.54%
Risk-free interest rate - maximum	4.51%	4.30%

Note 11 – Income Taxes

The provision (benefit) for income taxes is based on loss from operations before provision for income taxes and noncontrolling interests as follows (\$ in thousands):

	Years Ended December 31,	
	2025	2024
Pre-tax book income		
United States	\$ (16,890)	\$ (19,474)
Australia	(658)	(1,309)
Total	<u>\$ (17,548)</u>	<u>\$ (20,783)</u>

The provision (benefit) from income taxes was as follows (\$ in thousands):

	Years Ended December 31,	
	2025	2024
Current		
U.S. Federal	\$ —	\$ —
State and local	—	—
	<u>\$ —</u>	<u>\$ —</u>
Deferred		
U.S. Federal	\$ —	\$ —
State and local	(962)	(798)
	<u>\$ (962)</u>	<u>\$ (798)</u>
Total		
U.S. Federal	\$ —	\$ —
State and local	(962)	(798)
	<u>\$ (962)</u>	<u>\$ (798)</u>

The provision (benefit) for income taxes is determined by applying the U.S. Federal statutory rate of 21% to income before income taxes, and the components are set forth below (\$ in thousands):

	Years Ended December 31,			
	2025	%	2024	%
U.S. Federal tax (benefit) at statutory rate	\$ (3,685)	21.00 %	\$ (4,364)	21.00 %
Domestic				
Other true ups	(2)	0.01 %	(21)	0.10 %
Change in Valuation Allowance US	2,756	(15.71)%	3,695	(17.78)%
Non-taxable or non-deductible items				
Section 162(m) Limit on Compensation	67	(0.38)%	86	(0.41)%
Share-based compensation	525	(2.99)%	172	(0.83)%
Sale of NJ NOLs	202	(1.15)%	168	(0.81)%
Other	(1)	0.01 %	(11)	0.05 %
Domestic state and local income taxes, net of federal effect *	(962)	5.48 %	(798)	3.84 %
Foreign Tax Effects				
Australia				
AUS Foreign Rate Differential	(26)	0.15 %	(52)	0.25 %
Change in Valuation Allowance AUS	177	(1.01)%	(35)	0.17 %
Non-deductible R&D Expense	10	(0.06)%	188	(0.90)%
AUS Others	(23)	0.13 %	174	(0.84)%
Total Tax Provision	<u>\$ (962)</u>	<u>5.48 %</u>	<u>\$ (798)</u>	<u>3.84 %</u>

*State taxes in New Jersey made up the majority (greater than 50%) of the tax effect in this category.

Deferred income taxes at December 31, 2025 and 2024 consist of the following (\$ in thousands):

	December 31,	
	2025	2024
Deferred Tax Assets:		
Accumulated net operating losses (tax effected)	\$ 27,016	\$ 16,062
Lease liability	—	39
Share-based compensation	1,846	2,373
Intangibles	621	765
Capitalized research and development	548	7,717
Accumulated depreciation	18	21
Accrued payroll	197	219
Other	639	637
Deferred tax assets	30,885	27,833
Deferred Tax Liabilities:		
Right-of-use asset	\$ —	\$ (39)
Deferred tax liabilities	—	(39)
Net deferred tax asset	30,885	27,794
Valuation allowance	(30,885)	(27,794)
Net deferred tax asset	<u>\$ —</u>	<u>\$ —</u>

The following table presents income taxes paid, net of refunds received, disaggregated by jurisdiction for the years ended December 31, 2025 and 2024 (\$ in thousands):

Jurisdiction	Years Ended December 31,	
	2025	2024
U.S. Federal	\$ —	\$ —
States	—	—
New Jersey	4	4
California	2	2
Foreign	—	—
Total	<u>\$ 6</u>	<u>\$ 6</u>

In assessing the realizability of deferred tax assets, including the net operating loss carryforwards (NOLs), the Company assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to utilize its existing deferred tax assets. Based on its assessment, the Company has provided a full valuation allowance against its net deferred tax assets as their future utilization remains uncertain at this time.

As of December 31, 2025 and 2024, the Company had approximately \$99.0 million and \$57.9 million, respectively, of Federal NOLs available to offset future taxable income expiring from 2030 through 2036. The Company performed an analysis and determined that they had an ownership change of greater than 50% on September 15, 2022. As a result of the ownership change, losses incurred before the ownership change on September 15, 2022 will be subject to an annual limitation while losses incurred after September 15, 2022 will not be subject to limitations.

As of December 31, 2022, Cend Therapeutics, Inc. (“Cend”) had approximately \$3.6 million of Federal NOLs available to offset future taxable income. The Company performed an analysis and determined that there was an ownership change of greater than 50% on September 15, 2022. As of September 15, 2022 Cend has approximately \$3.1 million of Federal and \$4.3 million of state NOLs. The state NOLs will expire from the 2036 through 2042 tax years. Using a fair market value of \$36.1 million and applying an applicable federal rate of 2.54% Cend will have an annual limitation of approximately \$917 thousand each year. The Federal NOL of \$459 thousand incurred in the post-acquisition period September 15, 2022 to December 31, 2022 is not subject to limitation, and does not expire.

As of December 31, 2025 and 2024, the Company’s wholly owned Australian subsidiary had approximately \$3.0 million and \$2.3 million, respectively, of NOLs which will be carried forward and do not expire. There is a full valuation allowance against the NOLs.

As of December 31, 2025, the Company had federal research and development credit carryforwards of \$0.5 million expiring from 2027 through 2034 if unutilized, and state research and development credit carryforwards of \$0.1 million, which carryforward indefinitely. Utilization of these credits may be subject to an annual limitation based on changes in ownership.

As of December 31, 2025 and 2024, the Company had State NOLs available in New Jersey of \$54.8 million and \$24.6 million, respectively, California of \$9.2 million and \$9.2 million, respectively, and New York City of \$1.9 million and \$1.9 million, respectively, to offset future taxable income expiring from 2032 through 2045. The usage of the Company’s NOLs is limited given the change in ownership.

The Company applies the Financial Accounting Standards Board provisions for uncertain tax positions. The Company utilizes the two-step process to determine the amount of recognized tax benefit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the consolidated financial statements is the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the relevant taxing authority. The Company recognizes interest and penalties associated with certain tax positions as a component of income tax expense.

As of December 31, 2025 and 2024, the Company’s uncertain tax positions were \$344 thousand and \$344 thousand, respectively. The uncertain tax positions are due to the acquisition of Cend related to Federal and state credits and certain state NOLs. The Company will continue to evaluate its uncertain tax positions in future periods. The Company does not believe there will be any material changes in its unrecognized tax positions over the next year.

A reconciliation of the beginning and ending amounts of unrecognized tax benefits is as follows:

	Years Ended December 31,	
	2025	2024
Gross unrecognized tax benefit, beginning of period	\$ 344	\$ 344
Additions based on tax positions related to the current year	—	—
Additions based on tax positions related to the prior years	—	—
Reductions due to lapse in statute of limitations and settlements	—	—
Gross unrecognized tax benefit, end of period	<u>\$ 344</u>	<u>\$ 344</u>

For years prior to 2022 the federal statute of limitations is closed for assessing tax. The Company's state tax returns remain open to examination for a period of three to four years from the date of the tax return filing.

On March 4, 2024, the Company received final approval from the New Jersey Economic Development Authority ("NJEDA") under the Technology Business Tax Certificate Transfer Program ("Program") to sell \$8.9 million of its New Jersey net operating losses ("NJ NOLs"), which were subsequently sold to a qualifying and approved buyer pursuant to the Program for net proceeds of \$0.7 million. The sale of NJ NOLs resulted in a \$0.8 million deferred income tax benefit and a loss on sale of \$0.1 million recorded in other income (expense) in the consolidated financial statements.

In January 2025, the Company sold a portion of their unused New Jersey net operating losses through the State of New Jersey Economic Development Authority's ("NJEDA") Technology Business Tax Certificate Transfer Program ("Program"). Under the Program, the Company sold \$10.7 million of its New Jersey net operating losses ("NJ NOLs") for net proceeds of \$0.9 million. The sale of NJ NOLs resulted in a \$1.0 million deferred income tax benefit and a loss on sale of \$0.1 million recorded in other income (expense) in the consolidated financial statements.

On July 4, 2025, President Trump signed into law the One Big Beautiful Bill Act ("OBBBA"). The OBBBA makes permanent key elements of the Tax Cuts and Jobs Act, including 100% bonus depreciation, domestic research cost expensing, and the business interest expense limitation. ASC 740, "Income Taxes", requires the tax effects of changes in tax rates and tax law be recognized in the period in which the legislation is enacted. The Company completed its initial assessment of OBBBA for the year ended December 31, 2025. For the provisions effective in 2025, there was no material impact to the Company's effective tax rate for the year ended December 31, 2025.

The One Big Beautiful Bill Act ("OBBBA") enacted new Section 174A, which permanently allows taxpayers to fully expense domestic research or experimental (R&E) expenditures paid or incurred in taxable years beginning after Dec. 31, 2024, and also provides transition rules permitting taxpayers to deduct unamortized domestic R&E expenditures paid or incurred in 2022 through 2024. The company anticipates deducting the remaining unamortized domestic R&E expenditures of \$26.2 million entirely in 2025.

Note 12 – Segment Information

The Company operates as one operating segment, the research and development of its investigational drug product. The Company used the management approach to determine its reportable operating segment. The Company's Chief Operating Decision Maker ("CODM") is its Chief Executive Officer, who reviews financial information presented on a consolidated basis. The Company is a clinical-stage pharmaceutical company and has limited revenue associated with license and collaboration agreements. The CODM uses net loss as a measure of profit and loss, and assesses Company performance through the achievement of its clinical development goals. The CODM is regularly provided with budgeted and forecasted expense information which is used to determine the Company's liquidity needs and cash allocation to its development programs. The CODM uses cash and marketable securities as a measure of segment assets in managing the enterprise.

The Company had revenue of \$0.2 million during the year ended December 31, 2025, and \$1.0 million during the year ended December 31, 2024 in connection with certain upfront license fees in the current year and the Exclusive License and Collaboration Agreement with Kuva Labs, Inc in the prior year (Note 17) who is based in the United States. Depreciation and amortization expense was \$0.1 million and \$0.2 million for the years ended December 31, 2025, and 2024, respectively. Equity method investment expense was \$0.1 million for the year ended December 31, 2024. There was no equity method investment expense for the year ended December 31, 2025.

The following table illustrates our segment information for significant operating expenses and includes a reconciliation to net loss for the years ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
Revenue	\$ 170	\$ 1,000
Operating Expenses:		
Research and development by significant expense:		
BOLSTER trial	2,540	3,581
ASCEND trial	41	754
Chemistry, manufacturing and controls	1,050	2,035
Clinical department	2,999	4,304
Other ⁽¹⁾	1,319	660
Research and development	7,949	11,334
General and administrative by significant expense:		
Corporate	3,026	3,693
Investor relations/public relations/communications	1,141	1,332
Finance	2,002	2,265
Legal	919	1,284
Business development	422	582
Share based compensation expense	999	1,383
Other ⁽²⁾	1,921	1,536
General and administrative	10,430	12,075
Operating loss	(18,209)	(22,409)
Other income (expense),net	661	1,626
Benefit from income taxes	(962)	(798)
Net loss	\$ (16,586)	\$ (19,985)

Cash and marketable securities	\$ 15,956	\$ 31,245
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⁽¹⁾ Included in other are GBM study, FORTIFIDE study and research oncology expenses

⁽²⁾ Included in other are facilities expense, human resource, information technology expenses, allowance for credit losses and impairment of non-financial asset

Note 13 – Australia Research and Development Tax Incentive

The Company's Australian subsidiary, which conducts core research and development activities, is eligible to receive a refundable tax incentive between 43.5% to 48.5% (depending upon the income tax rate) for qualified research and development activities. As of December 31, 2025 and 2024, the Company had \$0.7 million and \$0.6 million, respectively, recorded as an income tax incentive receivable in prepaid and other current assets in the consolidated balance sheets, as the Company determined that the expenses met the eligibility criteria and the amounts claimed are expected to be received shortly after the related tax returns are filed. On February 4, 2026 the Company's Australian subsidiary received a \$0.7 million tax refund from the Australian Taxation Office related to the 2024 tax year.

Note 14 – Commitments and Contingencies

Second Amended and Restated Employment Agreement

On June 10, 2025, the Company entered into an amended and restated employment agreement with David J. Mazzo, Ph.D., the Company's Chief Executive Officer (the "Mazzo Second Amended and Restated Employment Agreement"). The Mazzo Second Amended and Restated Employment Agreement supplements and amends the Amended and Restated Employment Agreement, dated and effective as of March 19, 2021, between Dr. Mazzo and the Company.

The Mazzo Second Amended and Restated Employment Agreement: (i) amended Dr. Mazzo's base salary to \$717,229 from \$633,032 and removed the non-accountable expense allowance of \$12,000 per year, (ii) clarified that a material reduction in Dr. Mazzo's base salary is included in the definition of "Good Reason", (iii) amended that in the event of Dr. Mazzo's termination from the Company within two years following a Change in Control (as defined therein), any determination on (a) whether Dr. Mazzo's termination constitutes a termination with or without Cause (as defined therein) or with or without Good Reason (as defined therein) and (b) Dr. Mazzo's entitlement to the separation benefits and payments described therein, will be determined by the board of directors of the Company as constituted immediately prior to such Change in Control, which board may delegate its authority to a qualified independent third party, (iv) amended Dr. Mazzo's COBRA benefit coverage after the date of termination to monthly reimbursement payments for the cost of Dr. Mazzo's group health plan coverage, except in the event that such payment would incur tax penalties to the Company, violate applicable nondiscrimination requirements or in the event that the Company terminates the group health plan, in which case the Company will pay Dr. Mazzo a lump-sum cash payment equal to the aggregate cost of the remaining reimbursement payments less required withholdings, (v) amends the form of payment of Dr. Mazzo's bonus payments in the event of a termination not in connection to a Change in Control to a lump-sum payment, (vi) amended the definition of "Change in Control" therein to include the approval by the shareholders of the Company of any plan of complete liquidation of the Company, provided that the Change in Control meets all of the requirements of a "change in control" within the meaning of Treasury Regulation §1.409A-3(i)(5), (vii) clarified that the base salary severance payments, to the extent that the payments are in the aggregate less than or equal to twice the compensation limit under Section 401(a)(17) of the Internal Revenue Code of 1986, as amended (the "Code"), comply with the involuntary separation pay plan exception to Section 409A of the Code, and further clarified that Dr. Mazzo may receive such severance payments as a lump sum payment on the next payroll period following the date of his termination from employment; and (viii) clarified other technical terms for compliance with Section 409A of the Code.

Amended and Restated Employment Agreement

On June 10, 2025, the Company entered into an amended and restated employment agreement with Kristen K. Buck, M.D., the Company's Vice President, R&D and Chief Medical Officer (the "Buck Amended and Restated Employment Agreement"). The Buck Amended and Restated Employment Agreement supplemented and amended the Employment Agreement, dated and effective as of July 26, 2021, between Dr. Buck and the Company.

The Buck Amended and Restated Employment Agreement: (i) amended Dr. Buck's base salary to \$599,342 from \$550,000, (ii) clarified that a material reduction in Dr. Buck's base salary is included in the definition of "Good Reason", (iii) amended that in the event of Dr. Buck's termination from the Company within two years following a Change in Control (as defined therein), any determination on (a) whether Dr. Buck's termination constitutes a termination with or without Cause (as defined therein) or with or without Good Reason (as defined therein) and (b) Dr. Buck's entitlement to the separation benefits and payments described therein, will be determined by the board of directors of the Company as constituted immediately prior to such Change in Control, which board may delegate its authority to a qualified independent third party, (iv) amended Dr. Buck's COBRA benefit coverage after the date of termination to monthly reimbursement payments for the cost of Dr. Buck's group health plan coverage, except in the event that such payment would incur tax penalties to the Company, violate applicable nondiscrimination requirements or in the event that the Company terminates the group health plan, in which case the Company will pay Dr. Buck a lump-sum cash payment equal to the aggregate cost of the remaining reimbursement payments less required withholdings, (v) amended Dr. Buck's bonus payments in the event of a termination not in connection to a Change in Control such that the amount will not be pro-rated for the number of days Dr. Buck was employed in the year of termination of employment, (vi) amended the definition of "Change in Control" therein to include the approval by the shareholders of the Company of any plan of complete liquidation of the Company, provided that the Change in Control meets all of the requirements of a "change in control" within the meaning of Treasury Regulation §1.409A-3(i)(5), (vii) clarifies that the base salary severance payments, to the extent that the payments are in the aggregate less than or equal to twice the compensation limit under Section 401(a)(17) of the Code comply with the involuntary separation pay plan exception to Section 409A of the Code, and further clarified that Dr. Buck may receive such severance payments as a lump sum payment on the next payroll period following the date of her termination from employment; and (viii) clarified other technical terms for compliance with Section 409A of the Code.

Amended and Restated Separation Benefits Agreement

On June 10, 2025, the Company entered into an amended and restated separation benefits agreement with James Nisco, Senior Vice President Finance and Treasury and Chief Accounting Officer of the Company (the “Nisco Amendment”). The Nisco Amendment supplemented and amended the separation benefits provided in the Non-Change in Control Separation Pay Agreement between the Company and Mr. Nisco, dated as of December 24, 2024, and the severance agreement between Mr. Nisco and the Company, dated and effective as of September 12, 2016, and further amended on March 25, 2022.

The Nisco Amendment: (i) amended the definition of “Change in Control” therein to include the approval by the shareholders of the Company of any plan of complete liquidation of the Company, provided that the Change in Control meets all of the requirements of a “change in control” within the meaning of Treasury Regulation §1.409A-3(i)(5), (ii) included a condition that Mr. Nisco’s right to the severance payments and benefits described therein are subject to Mr. Nisco’s timely execution and non-revocation of a general release of claims within sixty days following Mr. Nisco’s termination or such shorter time period set forth therein, (iii) amended Mr. Nisco’s COBRA benefit coverage after the date of termination to monthly reimbursement payments for the cost of Mr. Nisco’s group health plan coverage, except in the event that such payment would incur tax penalties to the Company, violate applicable nondiscrimination requirements or in the event that the Company terminates the group health plan, in which case the Company will pay Mr. Nisco a lump-sum cash payment equal to the aggregate cost of the remaining reimbursement payments less required withholdings, (iv) amended that in the event of Mr. Nisco’s termination from the Company within two years following a Change in Control (as defined therein), any determination on (a) whether Mr. Nisco’s termination constitutes a termination with or without Cause (as defined therein) or with or without Good Reason (as defined therein) and (b) Mr. Nisco’s entitlement to the separation benefits and payments described therein, will be determined by the board of directors of the Company as constituted immediately prior to such Change in Control, which board may delegate its authority to a qualified independent third party, (v) clarified that the base salary severance payments, to the extent that the payments are in the aggregate less than or equal to twice the compensation limit under Section 401(a)(17) of the Code, comply with the involuntary separation pay plan exception to Section 409A of the Code, and further clarifies that Mr. Nisco may receive such severance payments as a lump sum payment on the next payroll period following the date of his termination from employment; and (vi) clarified other technical terms for compliance with Section 409A of the Code.

Amended and Restated Separation Benefits Agreement

On June 10, 2025, the Company entered into an amended and restated separation benefits agreement (the “Imam Amendment”) with Tariq Imam, Senior Vice President, Business Development and Operations and General Counsel of the Company. The Imam Amendment supplemented and amended the separation benefits provided in the Non-Change in Control Separation Pay Agreement between the Company and Mr. Imam, dated as of December 24, 2024, effective as of February 1, 2025 (the “Imam Non-Change in Control Separation Pay Agreement”) and the severance agreement between Mr. Imam and the Company, dated as of March 25, 2022 (the “Imam Severance Agreement”).

Imam Severance Agreement

Pursuant to the Imam Severance Agreement, Mr. Imam is entitled to receive certain payments following his termination from the Company in specific circumstances. If Mr. Imam terminates his employment for Good Reason (as defined in the Imam Severance Agreement) during the period commencing on the effective date of a Change in Control (as defined in the Imam Severance Agreement) and ending on the second anniversary of the effective date of a Change in Control (as defined in the Imam Severance Agreement), or the Company terminates Mr. Imam’s employment without Cause (as defined in the Imam Severance Agreement) (other than by reason of his death or disability), the Company will (a) continue to pay Mr. Imam’s current base salary of \$356,000 (the “Imam Salary Payment”) for 12 months following the date the termination becomes effective (the “Imam Severance Period”), commencing on the next payroll period following the date the termination becomes effective and (b) pay Mr. Imam a lump-sum equal to 100% of Mr. Imam’s then annual target bonus on the next payroll period following the date the termination becomes effective (the “Imam Cash Severance”) and (c) pay monthly the monthly premium amount for continued COBRA coverage. If the Company may not pay Mr. Imam’s COBRA premiums without incurring tax penalties or violating any requirement of law, the Company shall use its commercially reasonable best efforts to provide Mr. Imam with substantially similar assistance in an alternative manner (the “Imam COBRA Payments”), provided that the cost of doing so does not exceed the cost that the Company would have incurred had the Company been able to pay the COBRA premiums on Mr. Imam’s behalf. In addition to the Imam Salary Payment, Imam Cash Severance and the Imam COBRA Payments, the Company shall (i) fully vest as of the date the termination becomes effective, all outstanding unvested equity awards, including options granted to Mr. Imam; and (ii) extend the exercise date of the options to the earlier of the one-year anniversary of the date the termination becomes effective and the original expiration date of the options.

Imam Non-Change in Control Separation Pay Agreement

Pursuant to the Imam Non-Change in Control Separation Pay Agreement, Mr. Imam is entitled to a salary continuation of his current base salary of \$356,000 for 12 months from the date of his termination, as well as a lump-sum cash payment of 100% of his then annual target bonus on the next payroll period following the date the termination becomes effective. Mr. Imam is also entitled to payment of accrued but unpaid paid time off and wages up to the date of termination and monthly COBRA coverage reimbursements for 12 months from the date of termination. The Imam Non-Change in Control Separation Pay Agreement also provides an extension of the time period for exercising any fully vested option awards to the earlier of the one-year anniversary of the date the termination becomes effective and the original expiration date of the options.

The Imam Amendment: (i) amended the definition of “Change in Control” therein to include the approval by the shareholders of the Company of any plan of complete liquidation of the Company, provided that the Change in Control meets all of the requirements of a “change in control” within the meaning of Treasury Regulation §1.409A-3(i)(5), (ii) included a condition that Mr. Imam’s right to the severance payments and benefits described therein are subject to Mr. Imam’s timely execution and non-revocation of a general release of claims within sixty days following Mr. Imam’s termination or such shorter time period set forth therein, (iii) amended Mr. Imam’s COBRA benefit coverage after the date of termination to monthly reimbursement payments for the cost of Mr. Imam’s group health plan coverage, except in the event that such payment would incur tax penalties to the Company, violate applicable nondiscrimination requirements or in the event that the Company terminates the group health plan, in which case the Company will pay Mr. Imam a lump-sum cash payment equal to the aggregate cost of the remaining reimbursement payments less required withholdings, (iv) clarified that in the event of Mr. Imam’s termination from the Company within two years following a Change in Control (as defined therein), any determination on (a) whether Mr. Imam’s termination constitutes a termination with or without Cause (as defined therein) or with or without Good Reason (as defined therein) and (b) Mr. Imam’s entitlement to the separation benefits and payments described therein, will be determined by the board of directors of the Company as constituted immediately prior to such Change in Control, which board may delegate its authority to a qualified independent third party, (v) clarified that the base salary severance payments, to the extent that the payments are in the aggregate less than or equal to twice the compensation limit under Section 401(a)(17) of Code, comply with the involuntary separation pay plan exception to Section 409A of the Code, and further clarifies that Mr. Imam may receive such severance payments as a lump sum payment on the next payroll period following the date of his termination from employment and (vi) clarified other technical terms for compliance with Section 409A of the Code.

Legal Proceedings and Claims

From time to time, the Company is subject to legal proceedings and claims, either asserted or unasserted, that arise in the ordinary course of business. While the outcome of pending claims cannot be predicted with certainty, the Company does not believe that the outcome of any pending claims will have a material adverse effect on the Company's financial condition or operating results. The Company has elected to recognize expense for legal fees as incurred when the legal services are provided.

In May 2021, Cend received a written threat of litigation on behalf of a Chinese entity called Lingmed Limited (“Lingmed”) claiming Lingmed was entitled to a success fee based on Cend’s Collaboration and License Agreement with Qilu Pharmaceuticals. Cend responded by denying that Lingmed is entitled to a success fee under the terms of their agreement. In May 2022, Cend was served with a complaint filed by Lingmed in the San Diego County Superior Court, alleging claims for breach of contract, fraud and declaratory relief. Cend’s response to the complaint was filed on June 6, 2022 and denied all of Lingmed’s material allegations. Lingmed filed an answer to Cend’s response on July 11, 2022, denying all of the Company’s material allegations. On March 25, 2024 the Company entered into a settlement agreement whereby the Company was required to pay Lingmed \$0.5 million within 30 days of the effective date and the Company effected payment on April 4, 2024. Lingmed is also entitled to 5.0% of any future milestone payments received by the Company under the license agreement with Qilu in addition to a sum of \$250 thousand with respect to the first future milestone received by the Company. On April 9, 2024, pursuant to the parties’ joint request, the Court entered a dismissal with prejudice of the entire action as to all parties and all claims and the matter was settled. On January 23, 2026, the Company entered into a mutual termination of the Collaboration and License Agreement with Qilu Pharmaceuticals.

Note 15 – Technology Transfer Agreement

Impilo Therapeutics

In July 2023, the Company entered into a technology transfer agreement with Impilo Therapeutics (“Impilo”) under which the Company transferred its rights to its tumor penetrating nanocomplex (TPN) platform to Impilo. As consideration for the technology transfer, Impilo issued a total of 766,000 shares of its pre-seed preferred stock to the Company. On October 3, 2023 in connection with the Sanford Burnham Prebys license agreement (see Note 16 - License Agreements) Impilo cancelled the original stock certificate for 766,000 shares and reissued 574,500 shares of its pre-seed preferred stock to the Company.

On March 15, 2024, the Company purchased a Simple Agreement for Future Equity (“SAFE”) from Impilo for \$100 thousand. On July 12, 2024, the Company purchased an additional SAFE from Impilo for \$30 thousand. As of December 31, 2025 and December 31, 2024 the Company owned 38.6% of Impilo. These investments were expensed under the equity method of accounting in the prior year in other expense, net in the accompanying statement of operations. The SAFE has a valuation cap of \$30.0 million and an 80% discount rate.

Note 16 – License Agreements

Sanford Burnham Prebys

In December 2015, Cend entered into a license agreement with Sanford Burnham Prebys (“SBP”) under which Cend was granted an exclusive, worldwide, royalty-bearing license to certain patent rights and know-how controlled by SBP related to the development of certepetide. At the time the license agreement was entered into, Cend’s founding shareholder was an executive at SBP. The agreement provides the Company with the rights to grant and authorize sublicenses to use, sell, and otherwise exploit the patent rights. As consideration for the license, SBP was issued a total of 382,030 shares of common stock. The Company is required to pay an annual license maintenance fee of \$10 thousand increasing to \$20 thousand on year seven of the agreement. The Company could also be required to make milestone payments to SBP upon completion of certain regulatory and commercial milestones. The aggregate potential milestone payments are approximately \$10.6 million. The Company has also agreed to pay SBP royalties of 4% of net sales of products sold by the Company, or through a sublicense, subject to certain reductions. Additionally, the Company is obligated to pay SBP 25% of any sublicensing income received, which, pursuant to the technology transfer agreement with Impilo, resulted in SBP receiving 191,500 shares of the Company’s pre-seed preferred stock in Impilo on October 3, 2023.

The agreement will expire upon the later of (i) the final abandonment of all pending patent applications within the licensed patents or (ii) the expiration of the last to expire patent within the licensed patents. The agreement may be terminated in its entirety by the Company at any time by giving SBP sixty days’ prior written notice. The agreement may be terminated in its entirety by SBP if the Company, at any time, defaults in the payment of any sum when due and fails to make such payment within thirty days after receipt of written notice. The agreement may be terminated in its entirety by either SBP or the Company (i) in the event of an uncured material breach by the other party, or (ii) in the event the other party (a) files for, or is involuntarily petitioned with, bankruptcy (other than dissolution or winding up for the purposes of reconstruction or amalgamation), (b) makes an assignment of all or substantially all of its assets for the benefit of creditors, or (c) has a receiver or trustee is appointed and is unable to secure a dismissal, stay or other suspension of such proceedings within thirty days. Upon termination of the agreement for any reason, all rights and obligations of the Company with respect to the patents and patent applications shall terminate and revert to SBP.

SBP did not own shares of the Company’s common stock as of December 31, 2025.

Note 17 – Research Collaboration and License Agreements

Exclusive License and Collaboration Agreement - Qilu Pharmaceutical

In February 2021, Cend entered into an Exclusive License and Collaboration Agreement (the “Qilu Agreement”) in which Cend granted an exclusive license to Qilu for the development and commercialization of certepetide in the Territory (defined as the Greater Area of China including China, Macau, Hong Kong, and Taiwan). Under the terms of the agreement, Qilu is solely responsible for the development of certepetide in its Territory. In consideration for the license, Qilu made an upfront payment of \$10.0 million to Cend, which was recognized as revenue by Cend prior to the Company's acquisition of Cend on September 15, 2022 (the “Cend Merger”). In addition, Cend received and recognized as revenue a \$5.0 million development milestone prior to the Cend Merger. The Company is eligible to receive additional development and commercial milestone payments up to

\$96.0 million and \$125.0 million, respectively, tiered royalties on net sales ranging from 10% to 15%, and tiered sublicensing revenues ranging from 12% to 35%.

On March 25, 2024 the Company entered into a settlement agreement with Lingmed whereby Lingmed is entitled to 5.0% of any future milestone payments received by the Company under the Qilu Agreement. In addition, Lingmed is entitled to a sum of \$250 thousand with respect to the first future milestone received by the Company.

Unless terminated early, the Qilu Agreement will continue in effect until the expiration of all Qilu payment obligations. Either party may terminate the Qilu Agreement if an undisputed material breach by the other party is not cured within a defined period of time, or upon notice for insolvency-related events of the other party that are not discharged within a defined time period. Qilu may terminate the Qilu Agreement in its entirety, at any time with at least sixty days written notice. All rights and obligations of Qilu with respect to such licensed patents and patent applications would terminate simultaneously. On January 23, 2026 the Company entered into a mutual termination of the February 2021 Exclusive License and Collaboration Agreement with Qilu Pharmaceutical Co., Ltd. This action resulted in all licenses and other rights granted to Qilu reverting to the Company.

Exclusive License and Collaboration Agreement - Kuva Labs

In November 2024, the Company entered into an Exclusive License and Collaboration Agreement (Agreement) in which the Company granted an exclusive license to Kuva Labs, Inc. (Kuva) to explore the synergistic potential of the Company's certepetide, as a targeting and delivery agent for Kuva's NanoMark™ imaging technology in solid tumors. Under the Agreement, Kuva will assume full responsibility for research, development, and commercialization costs, while the Company will be responsible for supplying certepetide for additional consideration pursuant to a Clinical Supply Agreement. In consideration for the license, the Company recognized \$1.0 million as revenue upon delivery of the license in November 2024. The Company was eligible to receive additional development and commercial milestone payments up to \$1.5 million and \$17.5 million, respectively, a 5.0% percent royalty on net sales, and sublicensing revenues of 50% On November 30, 2025, Kuva Labs defaulted for non-payment of its obligation under the Agreement, and were unable to satisfy such obligation during the cure period that expired on December 31, 2025. As a result of the default and failure to cure such default, the Agreement was terminated.

Non-Exclusive License Agreement - Catalent

On October 8, 2025, the Company entered into a worldwide Non-Exclusive License Agreement (the "Non-Exclusive License Agreement" or the "Agreement") with Catalent, Inc. ("Catalent"), pursuant to which the Company granted to Catalent, on a non-exclusive basis, certain of its intellectual property to exploit use of the Company's novel iRGD cyclic peptide, certepetide, as an antibody drug conjugate (ADC) payload as part of Catalent's SMARTag® ADC platform. Under the Agreement, Catalent will assume full responsibility for research, development, and commercialization costs. In connection with entering into the Non-Exclusive License Agreement, the Company is eligible to receive pre-determined development milestone payments of up to \$10.5 million in the aggregate. The Company is also eligible to receive tiered revenue sharing on future sales and/or partnerships, subject to specified royalty reductions as set forth in the Agreement, as well as a portion of any sublicense consideration received from the grant of any sublicense or similar rights under any of the rights or licenses granted to Catalent under the Agreement. The Agreement will remain in effect until it expires on a product-by-product and country-by-country basis at the end of the royalty term. Either party may terminate the Agreement upon the other party's material breach, subject to specified notice and cure provisions, as well as resulting from the bankruptcy or insolvency of the other party. Catalent may also terminate the Agreement in its entirety at any time by giving the Company at least thirty (30) days prior written notice. In connection with the Agreement, Catalent has agreed to grant the Company a right of first negotiation for a license, in the event Catalent initiates a specific, organized out-licensing process of an asset resulting from the Agreement.

Note 18 – Subsequent Events

Proposed Acquisition by Kuva Labs Inc.

On March 6, 2026, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") with Kuva Labs Inc. ("Kuva"), and Kuva Acquisition Corp., a wholly owned subsidiary of Kuva ("Purchaser"). Pursuant to the Merger Agreement, and upon the terms and subject to the conditions thereof, Purchaser will commence a tender offer (the "Offer") to purchase all of the issued and outstanding shares of common stock, par value \$0.001 per share (the "Common Shares"), of the Company in exchange for (i) \$5.00 per Common Share, net to the seller in cash, without interest, but subject to any applicable withholding of taxes (the "Closing Amount") plus (ii) one non-tradeable contingent value right (each, a "CVR"), which represents the contractual right to receive a contingent cash payment of \$1.00 per CVR if a New Drug Application or similar registration is filed or formally accepted for review by the FDA or any governmental authority in any jurisdiction with respect

to any pharmaceutical product that contains or incorporates the product candidate referred to as of the date of the Merger Agreement as certepetide, alone or in combination with one or more other therapeutically active ingredients, including all formulations, dosages, or modes of delivery, for any indication or patient population prior to the earlier of (a) 11:59 p.m. New York City Time on the seventh (7th) anniversary of the Closing Date (as defined in the Merger Agreement), and (b) termination of the CVR Agreement, (the Closing Amount plus one CVR, collectively, the “Offer Price”). If certain conditions are satisfied and the Offer is consummated, Kuva would acquire any remaining Shares for the Offer Price by a merger of Purchaser with and into the Company (the “Merger”). Upon completion of these transactions, the Company would no longer be a publicly traded company and the listing of its common stock on Nasdaq will terminate.

Under the Merger Agreement, the Offer and the Merger are subject to customary closing conditions for a transaction of this nature. Kuva will be required to close on the Offer so long as there shall be validly tendered a number of shares that represents (and will represent immediately following the consummation of the Offer) at least a majority of the aggregate voting power of all shares then outstanding. There can be no assurance that the Offer and the Merger will be consummated.

The foregoing description of the Merger Agreement is only a summary of certain material provisions thereof, does not purport to be complete. The full text of the Merger Agreement is filed as Exhibit 2.1 to this Annual Report on Form 10-K.

Termination of Exclusive License and Collaboration Agreement with Qilu Pharmaceutical

On January 23, 2026, the Company entered into a mutual termination of the February 2021 Exclusive License and Collaboration Agreement with Qilu Pharmaceutical Co., Ltd. This action resulted in all licenses and other rights granted to Qilu reverting to the Company.

Sale of New Jersey Net Operating Losses

On October 20, 2025, the Company received preliminary approval from the New Jersey Economic Development Authority (“NJEDA”) to participate in the Technology Business Tax Certificate Transfer Program (the “Program”). The Program permits qualified companies to sell a percentage of their New Jersey net operating losses (“NJ NOLs”) to unrelated profitable corporations. On February 15, 2026, the Company received final approval from the NJEDA, and it subsequently sold a portion of its NJ NOLs to a qualifying and approved buyer pursuant to the Program for net proceeds of \$0.3 million.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures

Disclosure controls and procedures are our controls and other procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934 (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934), as amended (the “Exchange Act”) is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports that we file under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer, who serves as our principal executive officer and who served as our principal financial officer until April 15, 2024, and our Senior Vice President, Finance and Treasury and Chief Accounting Officer, who has served as our principal financial officer from April 15, 2024 to present (together, the “Evaluating Officers”), as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Due to the inherent limitations of control systems, not all misstatements may be detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Controls and procedures can only provide reasonable, not absolute, assurance that the above objectives have been met.

As of December 31, 2025, we evaluated, with the participation of our management, including our Evaluating Officers, the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on that evaluation, our Evaluating Officers concluded that our disclosure controls and procedures were effective, at the reasonable assurance level, in ensuring that information required to be disclosed by us in the reports that we file or submit under

the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and is accumulated and communicated to management, including the Evaluating Officers, as appropriate to allow timely decisions regarding required disclosure.

Internal Control Over Financial Reporting

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act.

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of management and our board of directors; and
- 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.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to risk that controls may become inadequate because of changes in conditions or because of declines in the degree of compliance with policies or procedures.

Management assessed the effectiveness of its internal control over financial reporting as of December 31, 2025. In making this assessment, they used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in *Internal Control-Integrated Framework (2013)*.

As of December 31, 2025, based on management's assessment, our internal control over financial reporting was effective.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

During the three months ended December 31, 2025, no director or officer of the Company adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Management and Corporate Governance,” and “Code of Ethics” in our Proxy Statement for the 2026 Annual Meeting of Stockholders.

The following table sets forth the name and position of each of our executive officers and directors as of March 12, 2026.

Name	Position(s)
David J. Mazzo, Ph.D.	President and Chief Executive Officer and Class II Director
Kristen K. Buck, M.D.	Executive Vice President R&D and Chief Medical Officer
James Nisco	Senior Vice President, Finance and Treasury and Chief Accounting Officer
Tariq Imam	Senior Vice President, Business Development and Operations and General Counsel
Gregory B. Brown, M.D.	Class II Director; Chairman of Board of Directors
Steven M. Klosk	Class III Director
Cynthia L. Flowers	Class I Director
Heidi Henson	Class II Director
Mohammad Azab, MD, MBA	Class III Director

Executive Officers

David J. Mazzo, Ph.D.

David J. Mazzo, Ph.D. was appointed as our President and Chief Executive Officer on March 28, 2017. Dr. Mazzo was previously appointed as our Chief Executive Officer and as a member of our board of directors on January 5, 2015. Dr. Mazzo brings to Lisata over 40 years of experience in the pharmaceutical industry. Prior to joining Lisata, Dr. Mazzo served from August 2008 to October 2014 as Chief Executive Officer and as a member of the board of directors of Regado Biosciences, Inc. (Nasdaq: RGDO), a biopharmaceutical company focused on the development of novel antithrombotic drug systems for acute and sub-acute cardiovascular indications. Prior to his leading Regado, from March 2007 to April 2008, Dr. Mazzo was President, Chief Executive Officer and a director of Aeterna Zentaris, Inc. (Nasdaq: AEZS), a publicly held international biopharmaceutical company. From 2003 until 2007 Dr. Mazzo served as President, Chief Executive Officer and director of Chugai Pharma USA, LLC, a biopharmaceutical company and U.S. subsidiary of Chugai Pharmaceutical Co., Ltd. of Japan and a member of the Roche Group. Prior to that, Dr. Mazzo was Senior Vice President of Development Operations at the Schering-Plough Research Institute and was a director of the Essex Chimie European subsidiary at Schering-Plough Corporation, a publicly held pharmaceutical company that was subsequently acquired by Merck & Co., Inc. Earlier in his career, Dr. Mazzo held senior management and executive positions in R&D at Hoechst Marion Roussel, Inc., the U.S. subsidiary of Hoechst AG, that was subsequently acquired by Sanofi, a multinational pharmaceuticals company; and Rhone-Poulenc Rorer, Inc., a subsidiary of Rhone-Poulenc SA, a French pharmaceuticals company, that was subsequently acquired by Hoechst AG. He previously served on the board of directors of publicly held Visioneering Technologies, Inc., a developer and seller of therapeutic contact lenses for myopia progression control from February 2020 to February 2024 during which time he was Chairman of the board; EyePoint Pharmaceuticals, Inc., a biopharmaceutical company focused on treatments for diseases of the back of the eye, from October 2005 to June 2020 and was Chairman of the board from 2007 to 2018; Seneca Biopharmaceuticals, Inc., a therapeutics development company focused on CNS applications that merged with Palisade BIO, from April 2019 to April 2021 and Avanir Pharmaceuticals, Inc., a pharmaceutical company working in the area of products for CNS diseases, from October 2005 through January 2015, that was sold to Otsuka Holdings in 2015. He currently serves on the board of directors of Feldan Therapeutics, a private company developing technology for the intracellular delivery of therapeutic agents, where he has served on the board since January 2021 and as Chairman since October 2023.

Dr. Mazzo earned a B.A. in the Honors Program (Interdisciplinary Humanities) and a B.S. in Chemistry from Villanova University. In addition, Dr. Mazzo received his M.S. in chemistry and his Ph.D. degree in Analytical Chemistry from the

University of Massachusetts, Amherst. He was also a research fellow at the Ecole Polytechnique Federale de Lausanne, Switzerland.

Kristen K. Buck, M.D.

Dr. Kristen K. Buck joined Lisata in September 2021 as Executive Vice President of R&D and Chief Medical Officer (“CMO”) of the Company. Prior to joining Lisata, Dr. Buck worked at ICON plc from March 2020 to July 2021, where she served as its CMO and represented the company’s position on key scientific, ethical, and medical governance matters, provided guidance and oversight to the medical and scientific groups, and led the Drug Development Services group. Prior to that, Dr. Buck was Senior Vice President & Chief of Clinical Development at Optum Insights (part of the United Healthcare Group) from August 2018 to March 2020, where she led the clinical operations and regulatory groups within the Digital Research Network (DRN) clinical trial business. From January 2014 to July 2018, Dr. Buck held a position at Quintiles/IQVIA as Vice President of Global Strategic Drug Development designing clinical development plans and protocols across all therapeutic areas for emerging biotech and large pharma.

Earlier in her career, Dr. Buck worked as a primary care physician and then later served as a medical officer in the FDA’s Office of New Drugs Division of Gastrointestinal and Hematology Drug Products where she was responsible for reviewing efficacy and safety data for new drug indications, as well as post-marketing safety data for over 40 drugs. Dr. Buck worked at AstraZeneca for six years where she served as a Global Safety Physician and Global Study Physician, leading a large cardiovascular outcomes study through to commercialization. Her drug development experience covers every phase of development and over multiple therapeutic indications including cardiovascular/metabolic, rare diseases, gastrointestinal, pulmonary, neuroscience, oncology, immunology, and women’s health.

Dr. Buck currently serves as a Senior Medical Advisor and chairwoman of the Scientific Advisory Board for global contract research organization; Biorasi Inc. She also serves as a medical advisor to a private Canadian biotech company; Feldan Therapeutics.

Dr. Buck is a board certified and licensed physician who received her medical degree from the Pennsylvania State University School of Medicine and completed her internship and residency in Internal Medicine at Abington Memorial Hospital before working in a private practice as a primary care physician.

James Nisco

Mr. Nisco was appointed as our Senior Vice President, Finance and Treasury and Chief Accounting Officer on April 15, 2024. From August 2020 through April 2024, Mr. Nisco served as our Vice President of Finance & Treasury, and from February 2012 to August 2020, Mr. Nisco served as our Senior Director of Treasury, Financial Planning and Analysis. Mr. Nisco oversees all finance activities for the Company and is responsible for SEC reporting, financial reporting and accounting, treasury operations and financial planning and analysis.

With over 30 years of experience in corporate finance, Mr. Nisco has held various senior finance positions prior to Lisata, including at OSI Pharmaceuticals, Inc. (acquired by Astellas) and Ciba Corporation (acquired by The BASF Group). Mr. Nisco began his career at Ciba-Geigy (now Novartis Pharmaceuticals).

Mr. Nisco holds an MBA in Financial Management from Pace University and a Bachelor of Science in Business Economics from the State University of New York, College at Oneonta.

Tariq Imam

Mr. Imam was appointed as our Senior Vice President, Business Development and Operations and General Counsel in February 2025 and has served as Head of Business Development of the Company since May 2016. As of April 2023, Mr. Imam had also served as Corporate Counsel of the Company. Before joining Lisata, Mr. Imam led business and corporate development functions at various specialty pharmaceutical companies, including, Mist Pharmaceuticals, Leonard-Meron Biosciences (acquired by Citius Pharmaceuticals (NASDAQ: CTXR)), Akrimax Pharmaceuticals and Rouses Point Pharmaceuticals. Prior to that, Mr. Imam held positions of increasing responsibility at Humana (NYSE: HUM) within the corporate integration/M&A group. Mr. Imam also worked in the corporate finance and strategy division of Orion Health (ASX: OHE).

Mr. Imam’s legal career began in the areas of mergers and acquisitions, securities offerings, and other transactional work. Mr. Imam then went on to represent clients in civil matters such as contract, property, and family disputes, followed by practice in the areas of corporate restructuring, divestitures, and insolvency within the life sciences sector at an international law firm. Throughout his career, Mr. Imam has and continues to counsel individuals, small businesses, not-for-profit organizations, and emerging companies, through private advisement.

Mr. Imam holds an A.B. in Politics from Princeton University, a J.D. from the New York University School of Law and an MBA in Finance from the New York University Stern School of Business.

Non-Employee Directors

Gregory B. Brown, M.D.

Gregory B. Brown, M.D. was appointed to our board of directors in October 2016 and was elected Chairman by our board of directors on February 16, 2017. Dr. Brown is currently Chief Executive Officer of Memgen, Inc., a development-stage biotechnology company. In 2007, Dr. Brown co-founded HealthCare Royalty Partners (“HCR Partners”), a healthcare-focused private asset management firm investing in biopharmaceutical and medical products, and developing and deploying innovative risk-mitigated investment strategies to deliver non-correlated cash flow. Dr. Brown served as Vice Chairman of HCR Partners until December 2022 and remains a member of the firm’s SAB. Dr. Brown was educated as a transplantation immunologist and trained as a thoracic and vascular surgeon. He practiced thoracic and vascular surgery in a community setting where he also founded and led a health maintenance organization. He brings particular expertise in the scientific, technical, clinical and medical evaluation of products as well as in healthcare systems and payor/reimbursement dynamics. He has been involved in sourcing, performing due diligence on and closing more than \$1 billion of royalty financings.

Before co-founding HCR Partners, Dr. Brown was a partner at Paul Capital Partners where he co-managed that firm’s royalty investments as a member of the royalty management committee. Prior to beginning his principal investment career in 2003, Dr. Brown was co-head of investment banking and head of healthcare at Adams, Harkness & Hill (now Canaccord Genuity) and a ranked biotechnology research analyst at Vector Securities International. Dr. Brown holds a B.A. from Yale, an M.D. from SUNY Upstate Medical Center and an M.B.A. from Harvard Business School. He currently serves on the boards of Adimab, LLC since 2023, Memgen, Inc since 2018, and Aquestive Therapeutics since 2017. He previously served on the boards of FAST Biomedical, Cambrex Corporation, Faron Pharmaceuticals Oy, Invuity, Inc., and Vanderbilt Clinical S.a.r.l.

Steven M. Klosk

Steven M. Klosk joined our board of directors in 2014. He is a senior executive with extensive management experience in the life sciences industry. He served as a Director at Cambrex Corporation (NYSE:CBM) from May 2008 through December 2019, until it was acquired by Permira and then as Director from December 2019 until June 2020. Cambrex is one of the leading providers of active pharmaceutical ingredients, advanced intermediates and finished dosage form products to the branded and generic pharmaceutical markets, where he served as President and Chief Executive Officer from May 2008 through June 2020. In that role he was responsible for all aspects of Cambrex’s global business with manufacturing and R&D facilities in the United States, Sweden, Italy, Estonia, Canada, Scotland, and Germany.

From 2021 until April 2024, he served on the board of directors of Recipharm, a leading pharmaceutical contract development & manufacturing organization. Since 2021 he has served on the board of Formulated Solutions, a topicals contract development & manufacturing organization where he is the chairman of the board and BioIVT, a leading supplier of biologics specimens for biotech research. In addition, Mr. Klosk served on the board of Golden Arrow Merger Corp., which merged in August 2024 with Bolt Project Holdings Inc. (Nasdaq: BSLK), a pioneer in sustainable biomaterials for consumer products. Mr. Klosk served both as a board member and an audit committee member of Bolt Project Holdings until February 2025. Mr. Klosk previously served on the boards of BIOVECTRA, a leading small molecule and biologics CDMO until September 2024 and NJ Bio, a leading antibody drug conjugate contract research organization from March 2021 through December 2024.

Mr. Klosk held other executive positions at Cambrex Corporation, including President, Executive Vice President & COO as well as President, Pharma Business Unit (2007-2008) where he had full P&L and balance sheet responsibility for four operating units in North America and Europe. Prior to this he was Executive Vice President & COO Cambrex Pharma & Biopharmaceuticals Business Unit (2003-2007) where he was responsible for managing a highly profitable global business with six operating units in North America and Europe. Earlier in his career Mr. Klosk served as Vice President, Administration for The Genlyte Group, Inc., a publicly traded producer of lighting fixtures. Mr. Klosk earned a B.S. from Cornell University and a J.D. from New York Law School.

Cynthia L. Flowers

Ms. Flowers was appointed to our board of directors in November 2018. She is currently CEO of OMEZA Holdings, Inc., an advanced wound care company. From February 2014 through November 2017, Ms. Flowers was President and Chief Executive Officer of Ipsen North America, where she led the transformation of the company as it became the highest-growth subsidiary worldwide. Prior to joining Ipsen, she served as President of Eisai Pharmaceuticals, where she oversaw commercial operations, medical affairs and services, manufacturing, alliance management and other functions. She has also held general management roles, both domestically and internationally, at Amgen Inc. and Johnson & Johnson. Ms. Flowers began her career as an oncology/critical care nurse.

Ms. Flowers currently serves on the board of Hikma Pharmaceuticals PLC, a multigenerational generics company and G1 Therapeutics Inc., a biotechnology clinical development company. She has held positions on numerous corporate and non-profit boards, including Nanoform Finland OYi, a nanoparticle manufacturing company, Kadmon Group, Inc., a clinical stage biopharmaceutical company, the Women's Leadership Advisory Board for the John F. Kennedy School of Government at Harvard University and the board of directors for the Sarah Cannon Oncology Research Institute. Ms. Flowers holds an M.B.A. from the Wharton School of the University of Pennsylvania and a B.S.N. from the University of Delaware.

Heidi Henson

Ms. Henson was appointed to the Lisata Board in September 2022 and serves as the Chairman of the Audit Committee. Ms. Henson possesses over two decades of financial operations experience with both public and private companies. In addition, Ms. Henson currently serves on the board of directors of PepGen and Perspective Therapeutics.

Ms. Henson previously served as Chief Financial Officer at Pardes Biosciences where she was instrumental in completing their tender offer transaction, as well as their de-SPAC transaction. Prior to Pardes, she served as the Chief Financial Officer for Imbria Pharmaceuticals, Kura Oncology, Wellspring Biosciences, and their parent company, Araxes Pharma.

Ms. Henson holds a BS in Accounting from the University of San Diego and is a Certified Public Accountant (currently inactive) in California.

Mohammad Azab, MD, MBA

Mohammad Azab, M.D., MSc, MBA was appointed to our board of directors in September 2022. Dr. Azab is a leader in clinical and regulatory development of biopharmaceutical drugs with particular expertise in oncology drug development. In July 2009, Dr. Azab joined Astex Pharmaceuticals, Inc. ("Astex"), a pharmaceutical company focused on the discovery and development of drugs in oncology and other areas, as its Chief Medical Officer. Dr. Azab served as President and Chief Medical Officer of Astex from January 2014 to November 2020, and has served as the chair of its board of directors from November 2020 to May 1, 2022. Since January 2021, Dr. Azab has served on the board of directors of DURECT Corporation (Nasdaq: DRRX), a biopharmaceutical company committed to transforming the treatment of acute organ injury and chronic liver diseases. Additionally, Dr. Azab has served on the board of directors of Xenon Pharmaceuticals Inc. (Nasdaq: XENE), a biopharmaceutical company delivering innovative medicines to patients with neurological disorders, from January 2003 to June 2024. Previously, Dr. Azab served as President and Chief Executive Officer of Intradigm Corporation, a developer of siRNA cancer therapeutics. Prior to this, Dr. Azab served as Executive Vice President of Research and Development and Chief Medical Officer of QLT Inc. and in several leadership positions at AstraZeneca plc in the United Kingdom and Sanofi in France. Dr. Azab holds an MBA from the Richard Ivey School of Business, University of Western Ontario, and an MB ChB from Cairo University. He received post-graduate training and degrees in oncology research from the University of Paris-Sud and in biostatistics from the University of Pierre et Marie Curie in Paris, France.

ITEM 11. EXECUTIVE COMPENSATION

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Executive Compensation" and "Lisata Director Compensation" in our Proxy Statement for the 2026 Annual Meeting of Stockholders. The section entitled "Pay Versus Performance" in our 2026 Proxy Statement is not incorporated by reference herein.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The response to this item is incorporated by reference from the discussion responsive thereto under the caption "Security Ownership of Management and Certain Beneficial Owners" and "Equity Compensation Plan Information" in our Proxy Statement for the 2026 Annual Meeting of Stockholders.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Certain Relationships and Related Party Transactions" and "Governance of Lisata Therapeutics Inc." in our Proxy Statement for the 2026 Annual Meeting of Stockholders.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The response to this item is incorporated by reference from the discussion responsive thereto under the caption “Accounting Fees and Other Accounting Matters” in our Proxy Statement for the 2026 Annual Meeting of Stockholders.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

The following documents are being filed as part of this Annual Report:

(a)(1) FINANCIAL STATEMENTS:

Reference is made to the Index to Financial Statements on Page 76 of this Annual Report.

All other schedules have been omitted because the required information is not present or is not present in amounts sufficient to require submission of the schedule, or because the information required is included in the Financial Statements or Notes thereto.

(a)(3) EXHIBITS:

The following is a list of exhibits filed (or furnished, where specified) as part of this Annual Report on Form 10-K. Exhibits that were previously filed are described below and are incorporated by reference. For exhibits incorporated by reference, the location of the exhibit in the previous filing is indicated.

Exhibit	Description
2.1 *	Agreement and Plan of Merger, dated March 6, 2026, by and among the Company, Kuva Labs, Inc. and Kuva Acquisition Corp. (filed as Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the SEC on March 9, 2026).
3.1	Certificate of Amendment (Reverse Stock Split) to the Amended and Restated Certificate of Incorporation, dated September 14, 2022 (filed as Exhibit 3.1 to the Company's Current Report on 8-K, filed with the SEC on September 15, 2022).
3.2	Certificate of Amendment (Name Change) to the Amended and Restated Certificate of Incorporation, dated September 15, 2022 (filed as Exhibit 3.2 to the Company's Current Report on Form 8-K, filed with the SEC on September 15, 2022).
3.3	Amended and Restated Certificate of Incorporation of Lisata Therapeutics, Inc., as amended, effective July 27, 2016 (filed as Exhibit 3.1 to the Company's on Form 10-Q for the quarter ended June 30, 2016, filed with the SEC on August 9, 2016).
3.4	Amended and Restated By-Laws of the Lisata Therapeutics, Inc. as amended, effective as of July 27, 2016 (filed as Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, filed with the SEC on August 9, 2016).
3.5	Amendments to Amended and Restated Bylaws of Lisata Therapeutics, Inc., effective as of September 18, 2017 (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on September 21, 2017).
4.1	Description of Capital Stock (filed as Exhibit 4.3 to the Company's Annual Report on Form 10-K, for the year ended December 31, 2019, filed with the SEC on March 5, 2020).
4.2	Form of Warrant (filed as Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on April 24, 2020).
4.3	Form of Warrant (filed as Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on May 26, 2020).
4.4	Form of Warrant (filed as Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on July 10, 2020).
4.5	Form of Warrant (filed as Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on January 25, 2021).
10.1 +	Director Compensation Policy, dated April 21, 2021 (filed as Exhibit 10.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 30, 2023).
10.2 +	2018 Equity Incentive Compensation Plan, effective June 20, 2018, as amended on June 18, 2020, June 16, 2021, September 15, 2022, June 14, 2023 and June 27, 2024.
10.3 +	2015 Equity Incentive Compensation Plan, effective July 15, 2015 (filed as Exhibit 10.4 to the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 30, 2023).
10.4 +	Amended & Restated 2009 Equity Compensation Plan, effective October 4, 2012 (filed as Exhibit 10.5 to the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 30, 2023).

- 10.5 + 2017 Employee Stock Purchase Plan, effective as of March 28, 2017, as amended on June 20, 2018, June 14, 2023 and June 27, 2024.
- 10.6 + Form of Indemnification Agreement between the Company and each of its directors and officers (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on September 15, 2022).
- 10.7 + Amended and Restated Employment Agreement with David J. Mazzo, dated March 19, 2021 (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on March 19, 2021).
- 10.8 + Second Amended and Restated Employment Agreement, by and between the Company and David J. Mazzo, Ph.D., dated as of June 10, 2025 (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on June 13, 2025)
- 10.9 + Amended and Restated Employment Agreement, by and between the Company and Kristen K. Buck, M.D., dated as of June 10, 2025 (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on June 13, 2025).
- 10.10 + Amended and Restated Separation Benefits Agreement, by and between the Company and James Nisco, dated as of June 10, 2025 (filed as Exhibit 10.3 to the Company's Current Report on Form 8-K, filed with the SEC on June 13, 2025).
- 10.11 + Amended and Restated Separation Benefits Agreement, by and between the Company and Tariq Imam, dated as of June 10, 2025 (filed as Exhibit 10.4 to the Company's Current Report on Form 8-K, filed with the SEC on June 13, 2025).
- 10.12 Cend 2016 Equity Incentive Plan, including all amendments thereto (filed as Exhibit 99.1 to the Company's Registration Statement on Form S-8, filed with the SEC on October 17, 2022).
- 10.13 At The Market Offering Agreement, dated June 4, 2021, by and between Caladrius Biosciences, Inc. and H.C. Wainwright & Co., LLC (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on June 4, 2021).
- 10.14 Exclusive License Agreement, dated December 1, 2015, by and between Cend Therapeutics, Inc. (f/k/a DrugCendR, LLC) and Sanford Burnham Prebys Medical Discovery Institute (filed as Exhibit 10.18 to the Company's Registration Statement on Form S-4, filed with the SEC on June 15, 2022).
- 10.15 First Amendment to Exclusive License Agreement, dated March 8, 2016, by and between Cend Therapeutics, Inc. (f/k/a DrugCendR, LLC) and Sanford Burnham Prebys Medical Discovery Institute (filed as Exhibit 10.19 to the Company's Registration Statement on Form S-4, filed with the SEC on June 15, 2022).
- 10.16 Second Amendment to Exclusive License Agreement, dated May 10, 2019, by and between Cend Therapeutics, Inc. (f/k/a DrugCendR, LLC) and Sanford Burnham Prebys Medical Discovery Institute (filed as Exhibit 10.20 to the Company's Registration Statement on Form S-4, filed with the SEC on June 15, 2022).
- 10.17 Third Amendment to Exclusive License Agreement, dated September 24, 2020, by and between Cend Therapeutics, Inc. (f/k/a DrugCendR, LLC) and Sanford Burnham Prebys Medical Discovery Institute (filed as Exhibit 10.21 to the Company's Registration Statement on Form S-4, filed with the SEC on June 15, 2022).
- 10.18 Exclusive License and Collaboration Agreement, dated as of November 30, 2024, by and between Lisata Therapeutics, Inc. and Kuva Labs, Inc.
- 10.19 Non-Exclusive License Agreement, dated as of October 8, 2025, by and between Lisata Therapeutics, Inc. and Catalent, Inc.
- 14.1 Code of Ethics for Senior Financial Officers, effective as of November 7, 2022 (filed as Exhibit 14.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 30, 2023).

- 19.1 Insider Trading Policy, effective as of October 30, 2015 (filed as Exhibit 19.1 on the Company's Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 29, 2024).
- 97 Incentive Recoupment Policy, effective as of March 28, 2023 (filed as Exhibit 97 to the Company's Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 29, 2024).
- 21.1 Subsidiaries of Lisata Therapeutics, Inc.
- 23.1 Consent of Grant Thornton LLP.
- 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 pursuant to 18 U.S.C. Section 1350, as adopted pursuant Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 † Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant Section 906 of the Sarbanes-Oxley Act of 2002.

- 101.INS XBRL Instance Document
- 101.SCH XBRL Taxonomy Extension Schema
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase
- 101.DEF XBRL Taxonomy Extension Definition Linkbase
- 101.LAB XBRL Taxonomy Extension Label Linkbase
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase

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- + Management contract or compensatory plan, contract or arrangement required to be filed as an exhibit to this Form 10-K pursuant to Item 15(b) of Form 10-K.
 - † Furnished herewith.
 - * Schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company agrees to furnish supplementally a copy of any such schedule or exhibit to the SEC upon request.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in Basking Ridge (Bernards Township), State of New Jersey, on March 12, 2026.

LISATA THERAPEUTICS, INC.

By: /s/ David J. Mazzo, PhD

Name: David J. Mazzo
Title: President & Chief Executive Officer
(Principal Executive Officer)

Pursuant to the requirements of the Securities 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
<u>/s/ David J. Mazzo</u> David J. Mazzo, PhD	Director and President and Chief Executive Officer (Principal Executive Officer)	March 12, 2026
<u>/s/ James Nisco</u> James Nisco	SVP, Finance and Treasury and Chief Accounting Officer (Principal Financial Officer and Principal Accounting Officer)	March 12, 2026
<u>/s/ Gregory B. Brown</u> Gregory B. Brown, MD	Chairman of the Board of Directors	March 12, 2026
<u>/s/ Mohammad Azab</u> Mohamad Azab, MD, MBA	Director	March 12, 2026
<u>/s/ Cynthia L. Flowers</u> Cynthia L. Flowers, MBA	Director	March 12, 2026
<u>/s/ Heidi Henson</u> Heidi Henson	Director	March 12, 2026
<u>/s/ Steven M. Klosk</u> Steven M. Klosk, JD	Director	March 12, 2026

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A
(Amendment No. 1)

(Mark One)

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

FOR THE FISCAL YEAR ENDED December 31, 2025

OR

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

For the Transition Period from _____ to _____

Commission File Number 001-33650

LISATA THERAPEUTICS, INC.
(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

22-2343568
(I.R.S. Employer
Identification No.)

P.O. Box 173, Liberty Corner, New Jersey
(Address of principal executive offices)

07938
(zip code)

Registrant's telephone number, including area code: 908-842-0100

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, par value \$0.001 per share	LSTA	The 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 15(d) of the Securities Exchange Act of 1934. 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 and 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 and post 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 definition of “large accelerated filer,” “accelerated filer,” and “smaller reporting company” in Rule 12b-2 of the Exchange Act:

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

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

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

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

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

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

The aggregate market value of the Registrant's voting and non-voting common stock held by non-affiliates of the Registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to June 30, 2025 (the last business day of the Registrant's most recently completed second fiscal quarter) was approximately \$23.6 million, computed by reference to the last sale price of \$2.90 for the common stock on the Nasdaq Capital Market reported for such date. Shares held by executive officers, directors and persons owning directly or indirectly more than 10% of the outstanding common stock have been excluded from the preceding number because such persons may be deemed to be affiliates of the Registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

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

Class	Outstanding as of April 28, 2026
Common stock, \$0.001 par value per share	9,106,391 shares

DOCUMENTS INCORPORATED BY REFERENCE

None.

EXPLANATORY NOTE

This registrant is filing this Amendment No. 1 ("Amendment No. 1") to its Annual Report on Form 10-K for the year ended December 31, 2025 as filed with the Securities and Exchange Commission (the "SEC") on March 12, 2026 (the "Original Filing") solely to include the information required by Item 10 - "Directors, Executive Officers and Corporate Governance," Item 11 - "Executive Compensation," Item 12 - "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters," Item 13 - "Certain Relationships and Related Transactions, and Director Independence" and Item 14 - "Principal Accounting Fees and Services" of Part III of Form 10-K, that was intentionally omitted from Part III of the Original Filing. The reference on the cover page of the Original Filing to the incorporation by reference of portions of our definitive proxy statement into Part III of the Original Filing is hereby deleted. Items 10, 11, 12, 13 and 14 of Part III of the Original Filing are amended and restated in their entirety as set forth in this Amendment No. 1. In addition, pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), we are including with this Amendment No. 1 certain currently dated certifications. Because no financial statements have been included in this Amendment No. 1 and this Amendment No. 1 does not contain or amend any disclosure with respect to Items 307 and 308 of Regulation S-K, paragraphs 3, 4 and 5 of the certifications have been omitted. We are not including the certifications under Section 906 of the Sarbanes-Oxley Act of 2002 as no financial statements are being filed with this Amendment No. 1. Except as described above, no other amendments are being made to the Original Filing. This Amendment No. 1 does not reflect events occurring after the March 12, 2026 filing of the Original Filing or modify or update the disclosure contained in the Original Filing in any way other than as required to reflect the amendments discussed above and reflected below. Accordingly, this Amendment No. 1 should be read in conjunction with the Original Filing and our other filings with the SEC.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Amendment No. 1 contains “forward-looking” statements within the meaning of the Private Securities Litigation Reform Act of 1995, as well as historical information. When used in this Amendment No. 1, statements that are not statements of current or historical fact may be deemed to be forward-looking statements, including, without limitation, all statements related to any expectations of revenues, expenses, cash flows, earnings or losses from operations, cash required to maintain current and planned operations, capital or other financial items; any statements of the plans, strategies and objectives of management for future operations; any plans or expectations with respect to product research, development and commercialization, including regulatory approvals; any other statements of expectations, plans, intentions or beliefs; and any statements of assumptions underlying any of the foregoing. Without limiting the foregoing, the words “plan,” “project,” “forecast,” “outlook,” “intend,” “may,” “will,” “expect,” “likely,” “believe,” “could,” “anticipate,” “estimate,” “continue,” “target,” or similar expressions or other variations or comparable terminology are intended to identify such forward-looking statements, although some forward-looking statements are expressed differently. We remind readers that forward-looking statements are merely predictions and therefore inherently subject to uncertainties and other factors and involve known and unknown risks that could cause the actual results, performance, levels of activity or our achievements or industry results, to be materially different from any future results, performance, levels of activity or our achievements or industry results expressed or implied by such forward-looking statements. Factors that could cause our actual results to differ materially from anticipated results expressed or implied by forward-looking statements include, among others:

- the proposed acquisition of our company by Kuva Labs, Inc., including the anticipated time frame for completion of the transaction;
- our ability to obtain sufficient capital or strategic business arrangements to fund our operations and expansion plans, including collecting amounts owed to us under various licensing and other strategic arrangements, meeting our financial obligations under various licensing and other strategic arrangements, the funding of our clinical trials for product candidates, and the commercialization of the relevant technology;
- our ability to build and maintain the management and human resources infrastructure necessary to support the operation and/or growth of our business;
- our ability to continue as a going concern;
- whether a market is established for our products and our ability to capture a meaningful share of this market;
- scientific, regulatory and medical developments beyond our control;
- our ability to obtain and maintain, as applicable, appropriate governmental licenses, accreditations or certifications or to comply with healthcare laws and regulations or any other adverse effect or limitations caused by government regulation of our business;
- whether any of our current or future patent applications result in issued patents, the scope of those patents and our ability to obtain and maintain other rights to technology required or desirable for the conduct of our business, and our ability to commercialize products without infringing upon the claims of third-party patents;
- whether any potential strategic or financial benefits of various licensing agreements will be realized;
- our ability to diversify our pipeline of development product candidates, which could include an acquisition, merger, business combination, in-license or other strategic transaction, and whether any of such efforts will result in us entering into or completing any transaction or that any such transaction, if completed, will add to shareholder value;
- the results of our development activities;
- our ability to complete our other planned clinical trials (or initiate other trials) in accordance with our estimated timelines due to delays associated with enrolling patients due to the novelty of the treatment, the size of the patient population, competition with other clinical trials for similar subjects, patient and/or investigator site availability and accessibility due to external macroenvironmental factors and the need of patients to meet the inclusion criteria of the trial or otherwise; and
- the extent to which any future public health crisis and their long-term effects may impact, directly or indirectly, our business, including our clinical trials and financial condition.

The factors discussed herein, including those risks described in “Item 1A. Risk Factors” and elsewhere in the Original Filing and in our other periodic filings with the SEC, which are available for review at www.sec.gov, could cause actual results and developments to be materially different from those expressed or implied by such statements. All forward-looking statements attributable to us are expressly qualified in their entirety by these and other factors. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date they were made. Except as required

by law, we undertake no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

TABLE OF CONTENTS

PART III	
ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE	<u>7</u>
ITEM 11. EXECUTIVE COMPENSATION	<u>16</u>
ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS	<u>29</u>
ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE	<u>31</u>
ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES	<u>32</u>
PART IV	
ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES	<u>34</u>
ITEM 16. FORM 10-K SUMMARY	<u>36</u>

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

DIRECTORS

The Lisata Board of Directors (the “Lisata Board”) currently consists of six members. Pursuant to our Amended and Restated Certificate of Incorporation, we have a classified Board which consists of three separate classes of directors. Each class serves a three-year term and until their successors are duly elected and qualified. The classes are elected on a rotating or staggered basis, with each class being elected at the annual meeting of stockholders coinciding with the expiration of that class’s term. Pursuant to the General Corporation Law of the State of Delaware (the “DGCL”), if a board of directors is classified, unless the certificate of incorporation otherwise provides, members of such board of directors may be removed by the stockholders before the expiration of their terms only for cause.

The following table sets forth certain information about the current directors of our Company. There are no family relationships among any of our directors and executive officers. For biographical information regarding our directors, see the discussion under “Biographical Information — Directors,” below.

Name	Age	Director Since
Gregory B. Brown, M.D.	72	2016
David J. Mazzo, Ph.D.	69	2015
Mohammad Azab, M.D., M.B.A.	70	2022
Cynthia L. Flowers	66	2018
Heidi Henson	60	2022
Steven M. Klosk	69	2014

Biographical Information - Directors

Class I Directors Continuing in Office until the 2026 Annual Meeting of Stockholders

Cynthia L. Flowers

Ms. Flowers was appointed to our board of directors in November 2018. She is currently CEO of OMEZA Holdings, Inc., an advanced wound care company. From February 2014 through November 2017, Ms. Flowers was President and Chief Executive Officer of Ipsen North America, where she led the transformation of the company as it became the highest-growth subsidiary worldwide. Prior to joining Ipsen, she served as President of Eisai Pharmaceuticals, where she oversaw commercial operations, medical affairs and services, manufacturing, alliance management and other functions. She has also held general management roles, both domestically and internationally, at Amgen Inc. and Johnson & Johnson. Ms. Flowers began her career as an oncology/critical care nurse.

Ms. Flowers currently serves on the board of Hikma Pharmaceuticals PLC, a multigenerational generics company and G1 Therapeutics Inc., a biotechnology clinical development company. She has held positions on numerous corporate and non-profit boards, including Nanoform Finland OYi, a nanoparticle manufacturing company, Kadmon Group, Inc., a clinical stage biopharmaceutical company, the Women’s Leadership Advisory Board for the John F. Kennedy School of Government at Harvard University and the board of directors for the Sarah Cannon Oncology Research Institute. Ms. Flowers holds an M.B.A. from the Wharton School of the University of Pennsylvania and a B.S.N. from the University of Delaware. We believe that Ms. Flowers is qualified to serve on the Lisata Board based on her pharmaceutical industry, management and scientific training and experience.

Class II Directors Continuing in Office until the 2027 Annual Meeting of Stockholders

Gregory B. Brown, M.D.

Gregory B. Brown, M.D. was appointed to our board of directors in October 2016 and was elected Chairman by our board of directors on February 16, 2017. Dr. Brown is currently Chief Executive Officer of Memgen, Inc., a development-stage

biotechnology company. In 2007, Dr. Brown co-founded HealthCare Royalty Partners (“HCR Partners”), a healthcare-focused private asset management firm investing in biopharmaceutical and medical products, and developing and deploying innovative risk-mitigated investment strategies to deliver non-correlated cash flow. Dr. Brown served as Vice Chairman of HCR Partners until December 2022 and remains a member of the firm’s SAB. Dr. Brown was educated as a transplantation immunologist and trained as a thoracic and vascular surgeon. He practiced thoracic and vascular surgery in a community setting where he also founded and led a health maintenance organization. He brings particular expertise in the scientific, technical, clinical and medical evaluation of products as well as in healthcare systems and payor/reimbursement dynamics. He has been involved in sourcing, performing due diligence on and closing more than \$1 billion of royalty financings.

Before co-founding HCR Partners, Dr. Brown was a partner at Paul Capital Partners where he co-managed that firm’s royalty investments as a member of the royalty management committee. Prior to beginning his principal investment career in 2003, Dr. Brown was co-head of investment banking and head of healthcare at Adams, Harkness & Hill (now Canaccord Genuity) and a ranked biotechnology research analyst at Vector Securities International. Dr. Brown holds a B.A. from Yale, an M.D. from SUNY Upstate Medical Center and an M.B.A. from Harvard Business School. He currently serves on the boards of Adimab, LLC since 2023, Memgen, Inc since 2018, and Aquestive Therapeutics since 2017. He previously served on the boards of FAST Biomedical, Cambrex Corporation, Faron Pharmaceuticals Oy, Invuity, Inc., and Vanderbilt Clinical S.a.r.l. We believe that Dr. Brown is qualified to serve on the Lisata Board based on his medical, financial and management experience.

Heidi Henson

Ms. Henson was appointed to the Lisata Board in September 2022 and serves as the Chairman of the Audit Committee. Ms. Henson possesses over two decades of financial operations experience with both public and private companies. In addition, Ms. Henson currently serves on the board of directors of PepGen and Perspective Therapeutics.

Ms. Henson previously served as Chief Financial Officer at Pardes Biosciences where she was instrumental in completing their tender offer transaction, as well as their de-SPAC transaction. Prior to Pardes, she served as the Chief Financial Officer for Imbria Pharmaceuticals, Kura Oncology, Wellspring Biosciences, and their parent company, Araxes Pharma.

Ms. Henson holds a BS in Accounting from the University of San Diego and is a Certified Public Accountant (currently inactive) in California. We believe that Ms. Henson is qualified to serve on the Lisata Board based on her extensive finance and public company experience.

David J. Mazzo, Ph.D.

David J. Mazzo, Ph.D. was appointed as President and Chief Executive Officer on March 28, 2017 having previously been named as our Chief Executive Officer and an executive director of our board of directors on January 5, 2015. Dr. Mazzo brings to Lisata over 40 years of experience in the pharmaceutical industry. Prior to joining Lisata, Dr. Mazzo served from August 2008 to October 2014 as Chief Executive Officer and as a member of the board of directors of Regado Biosciences, Inc. (Nasdaq: RGDO), a biopharmaceutical company focused on the development of novel antithrombotic drug systems for acute and sub-acute cardiovascular indications. Prior to his leading Regado, from March 2007 to April 2008, Dr. Mazzo was President, Chief Executive Officer and a director of Aeterna Zentaris, Inc. (Nasdaq: AEZS), a publicly held international biopharmaceutical company with facilities in Quebec, Canada and the USA. From 2003 until 2007 Dr. Mazzo served as President, Chief Executive Officer and director of Chugai Pharma USA, LLC, a biopharmaceutical company and U.S. subsidiary of Chugai Pharmaceutical Co., Ltd. of Japan, a member of the Roche Group. Prior to that, Dr. Mazzo was Senior Vice President of Development Operations at the Schering-Plough Research Institute and was a director of the Essex Chimie European subsidiary at Schering-Plough Corporation, a publicly held pharmaceutical company that was subsequently acquired by Merck & Co., Inc. Earlier in his career, Dr. Mazzo held senior management and executive positions in R&D at Hoechst Marion Roussel, Inc., the U.S. subsidiary of Hoechst AG, that was subsequently acquired by Sanofi, a multinational pharmaceuticals company; and Rhone-Poulenc Rorer, Inc., a subsidiary of Rhone-Poulenc SA, a French pharmaceuticals company, that was subsequently acquired by Hoechst AG. He previously served on the board of directors of publicly held Visioneering Technologies, Inc., a developer and seller of therapeutic contact lenses for myopia progression control from February 2020 to February 2024 during which time he was Chairman of the board; EyePoint Pharmaceuticals, Inc., a biopharmaceutical company focused on treatments for diseases of the back of the eye, from October 2005 to June 2020 and was Chairman of the board from 2007 to 2018; Seneca Biopharmaceuticals, Inc., a therapeutics development company focused on CNS applications that merged with Palisade BIO, from April 2019 to April 2021 and Avanir Pharmaceuticals, Inc., a pharmaceutical company working in the area of products for CNS diseases, from October 2005 through January 2015, that was sold to Otsuka Holdings in 2015. He currently serves on the board of directors of Feldan Therapeutics, a private company

developing technology for the intracellular delivery of therapeutic agents, where he has served on the board since January 2021 and as Chairman since October 2023.

Dr. Mazzo earned a B.A. in the Honors Program (Interdisciplinary Humanities) and a B.S. in Chemistry from Villanova University. In addition, Dr. Mazzo received his M.S. in chemistry and his Ph.D. degree in Analytical Chemistry from the University of Massachusetts, Amherst. He was also a research fellow at the Ecole Polytechnique Federale de Lausanne, Switzerland. Recently, Dr. Mazzo was named a PharmaVoice Top 100 award winner for 2024 in the Standout Leader category. He is bilingual: English (native) and French. Based on Dr. Mazzo's experience within the pharmaceutical industry and his executive experience, specifically his experience as Chief Executive Officer at other companies in the biopharmaceutical industry, as well as his service on other boards of directors in the healthcare industry in addition to his scientific training and experience, we believe that Dr. Mazzo is qualified to serve on the Lisata Board.

Class III Directors Continuing in Office until the 2028 Annual Meeting of Stockholders

Mohammad Azab, M.D., M.B.A.

Mohammad Azab, M.D., MSc, M.B.A. was appointed to our board of directors in September 2022. Dr. Azab is a leader in clinical and regulatory development of biopharmaceutical drugs with particular expertise in oncology drug development. In July 2009, Dr. Azab joined Astex Pharmaceuticals, Inc. ("Astex"), a pharmaceutical company focused on the discovery and development of drugs in oncology and other areas, as its Chief Medical Officer. Dr. Azab served as President and Chief Medical Officer of Astex from January 2014 to November 2020, and has served as the chair of its board of directors from November 2020 to May 1, 2022. Since January 2021, Dr. Azab has served on the board of directors of DURECT Corporation (Nasdaq: DRRX), a biopharmaceutical company committed to transforming the treatment of acute organ injury and chronic liver diseases. Additionally, Dr. Azab has served on the board of directors of Xenon Pharmaceuticals Inc. (Nasdaq: XENE), a biopharmaceutical company delivering innovative medicines to patients with neurological disorders, from January 2003 to June 2024. Previously, Dr. Azab served as President and Chief Executive Officer of Intradigm Corporation, a developer of siRNA cancer therapeutics. Prior to this, Dr. Azab served as Executive Vice President of Research and Development and Chief Medical Officer of QLT Inc. and in several leadership positions at AstraZeneca plc in the United Kingdom and Sanofi in France. Dr. Azab holds an MBA from the Richard Ivey School of Business, University of Western Ontario, and an MB ChB from Cairo University. He received post-graduate training and degrees in oncology research from the University of Paris-Sud and in biostatistics from the University of Pierre et Marie Curie in Paris, France. We believe that Dr. Azab is qualified to serve on the Lisata Board based on his substantial expertise in oncology drug development.

Steven M. Klosk, J.D.

Steven M. Klosk, J.D. joined our board of directors in 2014. He is a senior executive with extensive management experience in the life sciences industry. He served as a Director at Cambrex Corporation (NYSE:CBM) from May 2008 through December 2019, until it was acquired by Permira and then as Director from December 2019 until June 2020. Cambrex is one of the leading providers of active pharmaceutical ingredients, advanced intermediates and finished dosage form products to the branded and generic pharmaceutical markets, where he served as President and Chief Executive Officer from May 2008 through June 2020. In that role he was responsible for all aspects of Cambrex's global business with manufacturing and R&D facilities in the United States, Sweden, Italy, Estonia, Canada, Scotland, and Germany.

From 2021 until April 2024, he served on the board of directors of Recipharm, a leading pharmaceutical contract development & manufacturing organization. Since 2021 he has served on the board of Formulated Solutions, a topicals contract development & manufacturing organization where he is the chairman of the board and BioIVT, a leading supplier of biologics specimens for biotech research. In addition, Mr. Klosk served on the board of Golden Arrow Merger Corp., which merged in August 2024 with Bolt Project Holdings Inc. (Nasdaq: BSLK), a pioneer in sustainable biomaterials for consumer products. Mr. Klosk served both as a board member and an audit committee member of Bolt Project Holdings until February 2025. Mr. Klosk previously served on the boards of BIOVECTRA, a leading small molecule and biologics CDMO until September 2024 and NJ Bio, a leading antibody drug conjugate contract research organization from March 2021 through December 2024.

Mr. Klosk held other executive positions at Cambrex Corporation, including President, Executive Vice President & COO as well as President, Pharma Business Unit (2007-2008) where he had full P&L and balance sheet responsibility for four operating units in North America and Europe. Prior to this he was Executive Vice President & COO Cambrex Pharma & Biopharmaceuticals Business Unit (2003-2007) where he was responsible for managing a highly profitable global business with six operating units in North America and Europe. Earlier in his career Mr. Klosk served as Vice President, Administration for The Genlyte Group, Inc., a publicly traded producer of lighting fixtures. Mr. Klosk earned a B.S. from Cornell University and a J.D. from New York Law School. We believe that Mr. Klosk is qualified to serve on the Lisata Board based on his diversified management experience, particularly in the biopharmaceutical field.

EXECUTIVE OFFICERS

The following table sets forth certain information about the executive officers of our Company. There are no family relationships among any of our directors and executive officers. For biographical information regarding our executive officers, see the discussion under “Biographical Information — Executive Officers,” below.

Name	Age	Position
David J. Mazzo, Ph.D.	69	President and Chief Executive Officer
Kristen K. Buck, M.D.	52	Executive Vice President R&D and Chief Medical Officer
James Nisco	55	Senior Vice President Finance and Treasury and Chief Accounting Officer
Tariq Imam	43	Senior Vice President, Business Development and Operations and General Counsel

Biographical Information - Executive Officers

David J. Mazzo, Ph.D.

See the discussion under “Biographical Information - Directors” above.

Kristen K. Buck, M.D.

Dr. Kristen K. Buck joined Lisata in September 2021 as Executive Vice President of R&D and Chief Medical Officer (“CMO”) of the Company. Prior to joining Lisata, Dr. Buck worked at ICON plc from March 2020 to July 2021, where she served as its CMO and represented the company’s position on key scientific, ethical, and medical governance matters, provided guidance and oversight to the medical and scientific groups, and led the Drug Development Services group. Prior to that, Dr. Buck was Senior Vice President & Chief of Clinical Development at Optum Insights (part of the United Healthcare Group) from August 2018 to March 2020, where she led the clinical operations and regulatory groups within the Digital Research Network (DRN) clinical trial business. From January 2014 to July 2018, Dr. Buck held a position at Quintiles/IQVIA as Vice President of Global Strategic Drug Development designing clinical development plans and protocols across all therapeutic areas for emerging biotech and large pharma.

Earlier in her career, Dr. Buck worked as a primary care physician and then later served as a medical officer in the FDA’s Office of New Drugs Division of Gastrointestinal and Hematology Drug Products where she was responsible for reviewing efficacy and safety data for new drug indications, as well as post-marketing safety data for over 40 drugs. Dr. Buck worked at AstraZeneca for six years where she served as a Global Safety Physician and Global Study Physician, leading a large cardiovascular outcomes study through to commercialization. Her drug development experience covers every phase of development and over multiple therapeutic indications including cardiovascular/metabolic, rare diseases, gastrointestinal, pulmonary, neuroscience, oncology, immunology, and women’s health.

Dr. Buck currently serves as a Senior Medical Advisor and chairwoman of the Scientific Advisory Board for global contract research organization; Biorasi Inc. She also serves as a medical advisor to a private Canadian biotech company; Feldan Therapeutics.

Dr. Buck is a board certified and licensed physician who received her medical degree from the Pennsylvania State University School of Medicine and completed her internship and residency in Internal Medicine at Abington Memorial Hospital before working in a private practice as a primary care physician.

James Nisco

Mr. Nisco was appointed as our Senior Vice President, Finance and Treasury and Chief Accounting Officer on April 15, 2024. From August 2020 through April 2024, Mr. Nisco served as our Vice President of Finance & Treasury, and from February 2012 to August 2020, Mr. Nisco served as our Senior Director of Treasury, Financial Planning and Analysis. Mr. Nisco oversees all finance activities for the Company and is responsible for SEC reporting, financial reporting and accounting, treasury operations and financial planning and analysis.

With over 30 years of experience in corporate finance, Mr. Nisco has held various senior finance positions prior to Lisata, including at OSI Pharmaceuticals, Inc. (acquired by Astellas) and Ciba Corporation (acquired by The BASF Group). Mr. Nisco began his career at Ciba-Geigy (now Novartis Pharmaceuticals).

Mr. Nisco holds an MBA in Financial Management from Pace University and a Bachelor of Science in Business Economics from the State University of New York, College at Oneonta.

Tariq Imam

Mr. Imam was appointed as our Senior Vice President, Business Development and Operations and General Counsel in February 2025 and has served as Head of Business Development of the Company since May 2016. As of April 2023, Mr. Imam had also served as Corporate Counsel of the Company. Mr. Imam also assumed the role as the Company's Head of Human Resources in April 2025. Before joining Lisata, Mr. Imam led and supported business and corporate development functions at various clinical and commercial stage pharmaceutical companies, including, Mist Pharmaceuticals, Leonard-Meron Biosciences (acquired by Citius Pharmaceuticals (NASDAQ: CTXR)), Akrimax Pharmaceuticals and Rouses Point Pharmaceuticals. Prior to that, Mr. Imam held positions of increasing responsibility at Humana (NYSE: HUM) within the corporate integration/M&A group. Mr. Imam also worked in the corporate finance and strategy division of Orion Health (ASX: OHE).

Mr. Imam's legal career began in the areas of mergers and acquisitions, securities offerings, and other transactional work. Mr. Imam then went on to represent clients in civil matters such as contract, property, and family disputes, followed by practice in the areas of corporate restructuring, divestitures, and insolvency within the life sciences sector at an international law firm. Throughout his career, Mr. Imam has and continues to counsel individuals, small businesses, not-for-profit organizations, and emerging companies, through private advisement.

Mr. Imam holds an A.B. in Politics from Princeton University, a J.D. from the New York University School of Law and an MBA in Finance from the New York University Stern School of Business.

Governance of Lisata Therapeutics, Inc.

Director Independence

The current Lisata Board members consist of Dr. Brown, Dr. Azab, Ms. Flowers, Ms. Henson, Mr. Klosk and Dr. Mazzo. The Lisata Board has reviewed the materiality of any relationship that each of our directors has with Lisata, either directly or indirectly. Based upon this review, the Lisata Board has determined that Dr. Brown, Dr. Azab, Ms. Flowers, Ms. Henson and Mr. Klosk are each "independent directors," applying the definition of independence under the listing standards of Nasdaq.

Board Leadership Structure and Role in Risk Oversight

Dr. Brown serves as the Chairman of the Board. When present, our Chairman presides over all Lisata Board meetings. Dr. Brown coordinates with our Chief Executive Officer to set the agenda for Lisata Board meetings, chairs executive sessions of the independent directors, and performs any other duties assigned from time to time by the Lisata Board. We believe that the separation of the Chairman and Chief Executive Officer roles at Lisata enhances good corporate governance principles through reduction of conflicts of interest and greater board independence.

The Lisata Board oversees our risk management. This oversight is administered primarily through the following:

- The Lisata Board's review and approval of our business plans and budget (prepared and presented to the Lisata Board by the President and Chief Executive Officer and other management), including the projected opportunities and challenges facing our business;
- No less than quarterly review of our business developments, business plan implementation and financial results;
- Our Audit Committee's oversight of our internal controls over cybersecurity and financial reporting and its discussions with management and the independent accountants regarding the quality and adequacy of our internal controls and financial reporting; and
- Our Compensation Committee's review and approval of our executive officer compensation and its relationship to our business plans.

Insider Trading Policy and Prohibition on Hedging

We have an Insider Trading Policy that, among other things, governs the buying and selling of our securities by all of our personnel, including directors, officers and employees and certain other covered persons. Our policy is designed to prevent violations of insider trading laws by our personnel and to avoid even the appearance of improper conduct in this regard by our personnel. The policy prohibits covered persons from purchasing, selling, or otherwise disposing of our securities while in possession of material non-public information (except in limited circumstances, such as pursuant to a previously established trading plan). In addition, the policy prohibits all employees (including executives and directors) from engaging in any transaction in which they may profit from short-term speculative swings in the value of our securities, including any of the following activities: (1) “short sales” (selling borrowed securities that the seller hopes can be purchased at a lower price in the future) of our securities; (2) use of our securities to secure a margin or other loan; (3) transactions in our securities involving straddles, collars or other similar risk reduction or hedging devices; and (4) transactions in publicly traded options relating to our securities (i.e., options that are not granted by us). The policy includes quarterly and other trading blackouts and sets forth the procedures covered persons must follow before transacting in our securities, including pre-clearance by our Senior Vice President, Business Development and Operations, and General Counsel of all transactions by executive officers, directors, employees and certain other covered persons, as well as members of their households. Although we have not adopted an insider trading policy governing the purchase, sale, and/or other disposition of our securities by the Company, as part of the oversight of risk, the Board, or one or more of its Committees, approves any transaction, plan or arrangement by or with the Company with respect to our securities on a case-by-case basis, and as part of their procedures to review and approve any such transaction, plan or arrangement, the Board or Committee consults with legal counsel to ensure compliance with applicable insider trading laws, rules and regulations, and listing standards. A copy of the policy is filed as an exhibit to our Annual Report on Form 10-K for the year ended December 31, 2025 as filed with the SEC.

Committees

The Lisata Board has established (i) an Audit Committee, (ii) a Compensation Committee and (iii) a Nominating and Governance Committee. Each of these Committees has only independent directors as members. In addition, the Lisata Board has established a Science and Technology Committee for which it has not imposed any membership rules regarding director independence, and which committee assists with reviewing development and regulatory strategy, R&D staffing and budgets, and recommendations regarding business development opportunities.

Audit Committee

The Audit Committee consists of three directors: Ms. Henson (Chair), Ms. Flowers and Mr. Klosk. Each member of the committee is independent applying the definition of independence under the listing standards of Nasdaq and SEC regulations. The Audit Committee met five times during the year. Ms. Henson, Ms. Flowers and Mr. Klosk each qualify as an “audit committee financial expert” as defined by Item 407(d)(5)(ii) of Regulation S-K.

Pursuant to the terms of the Audit Committee charter, the Audit Committee is required to consist of at least three “independent” directors and shall serve at the pleasure of the Lisata Board. An “independent” director is defined as an individual who (a) is not our officer or salaried employee or an affiliate, (b) does not have any relationship that, in the opinion of the Lisata Board, would interfere with his or her exercise of independent judgment as an Audit Committee member, (c) meets the independence requirements of the SEC and Nasdaq or such other securities exchange or market on which our securities are traded and (d) except as permitted by the SEC and Nasdaq or such other securities exchange or market on which our securities are traded, does not accept any consulting, advisory or other compensatory fee from us. The Audit Committee’s charter requires the committee to oversee our accounting and financial reporting process, our system of internal controls regarding cybersecurity, finance, accounting, legal compliance and ethics, and the audits of our financial statements. A current copy of such charter is available to stockholders on our website, www.lisata.com. The primary duties of the Audit Committee consist of, among other things:

- serving as an independent and objective party to monitor our financial reporting process, internal control system, cybersecurity policy and disclosure control system;
- reviewing and appraising the audit efforts of our independent accountants;
- assuming direct responsibility for the appointment, compensation, retention and oversight of the work of the outside auditors and for the resolution of disputes between the outside auditors and our management regarding financial reporting issues;

- providing an open avenue of communication among the independent accountants, financial and senior management and the Lisata Board; and
- reviewing and approving all related party transactions.

Compensation Committee

Our Compensation Committee consists of three directors: Mr. Klosk (Chair), Dr. Brown and Ms. Henson. Each such member of the Compensation Committee is independent applying the definition of independence under the listing standards of Nasdaq. The Compensation Committee met six times during the year.

Each member of our Compensation Committee must (i) be one of our independent directors satisfying the independence requirements of Nasdaq and other applicable regulatory requirements; (ii) qualify as an “outside director” under Section 162(m) of the Internal Revenue Code of 1986 (the “Code”) and (iii) meet the requirements of a “non-employee director” for purposes of Section 16 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Except as permitted by Nasdaq, members of the Compensation Committee must not accept any consulting, advisory or the other compensatory fee from us or any of our subsidiaries. In determining whether a director is eligible to serve on the Compensation Committee, the Lisata Board must consider whether the director is affiliated with us, one of our subsidiaries or an affiliate of one of our subsidiaries to determine whether such affiliation would impair the director’s judgment as a member of the Compensation Committee.

The Compensation Committee oversees the determination of all matters relating to employee compensation and benefits and specifically determines and approves salaries, bonuses and equity-based compensation for our executive officers.

We have adopted a Compensation Committee charter which outlines the Compensation Committee’s primary duties which are to:

- evaluate the performance of the President and Chief Executive Officer considering, *inter alia*, achievement of committee-approved goals and objectives and determine and approve the President and Chief Executive Officer’s compensation based on this evaluation and such other factors as the Compensation Committee shall deem appropriate;
- determine and approve all executive officer compensation;
- approve the aggregate amounts and methodology for determination of all salary, bonus, and long-term incentive awards for all employees other than executive officers;
- review and recommend equity-based compensation plans to the full Board and approve all grants and awards thereunder;
- review and approve changes to our equity-based compensation plans other than those changes that require stockholder approval under the plans, the requirements of Nasdaq or any exchange on which our securities may be listed and/or any applicable law;
- review and recommend to the full Board changes to our equity-based compensation plans that require stockholder approval under the plans, the requirements of Nasdaq or any exchange on which our securities may be listed and/or any applicable law;
- review and approve changes in our retirement, health, welfare and other benefit programs that result in a material change in costs or the benefit levels provided;
- administer our equity-based compensation plans; and
- approve, as required by applicable law, the annual Compensation Committee report on executive compensation for inclusion in our proxy statement.

The Compensation Committee has the authority, in its sole discretion, to retain or obtain advice from compensation consultants, independent legal counsel and other advisers, and is directly responsible for the retention, termination, compensation and oversight of the work of any such consultant, counsel or other adviser. In selecting a consultant, counsel or other adviser, the Compensation Committee must, as required by Nasdaq rules, take into consideration all factors relevant to such person’s independence from management, including all factors that Nasdaq identifies in its listing standards.

Since March 2015, the Compensation Committee has engaged the services of Radford/AON (“**Radford**”), a national executive compensation consulting firm with expertise in the life science industry to review and provide recommendations

concerning all of the components of Lisata's executive and director compensation program. Radford performs services solely on behalf of the Compensation Committee and has no relationship with the Company or management except as may relate to performing such services. Radford assisted the Compensation Committee in defining the appropriate market of the Company's peer companies for executive compensation and practices and in benchmarking our executive compensation program against the peer group for 2024 and in years past compensation actions. Radford also assisted the Compensation Committee in benchmarking our director compensation program and practices against those of our peers. The Compensation Committee has assessed the independence of Radford pursuant to SEC rules and the corporate governance rules of Nasdaq and concluded that no conflict of interest exists that would prevent Radford from independently representing the Compensation Committee.

A current copy of the Compensation Committee charter is available to stockholders on our website, www.lisata.com. The Compensation Committee may form and delegate its authority to subcommittees as appropriate. Additionally, the President and Chief Executive Officer may make recommendations to the Compensation Committee relating to executive and director compensation, but consistent with Nasdaq rules, he may not be present during deliberations or voting regarding his own compensation.

Nominating and Governance Committee

Our Nominating and Governance Committee consists of three directors: Dr. Gregory Brown (Chair), Dr. Azab and Ms. Flowers. The Nominating and Governance Committee is empowered by the Lisata Board to recommend to the Lisata Board qualified individuals to serve on the Lisata Board and to identify the manner in which the Nominating and Governance Committee evaluates nominees recommended for the Lisata Board. All members of the Nominating and Governance Committee have been determined to be "independent directors" pursuant to the definition contained in the rules of Nasdaq and SEC regulations. The Nominating and Governance Committee met four times during the year.

The Lisata Board has adopted a Nominating and Governance Committee charter to govern the Nominating and Governance Committee, a current copy of which is available to stockholders on our website, www.lisata.com.

Additional Board Committee

The Lisata Board also maintains the following additional committee:

Science and Technology Committee

The Science and Technology Committee consists of Drs. Azab (Chairman), Brown, and Mazzo. This committee is authorized to review the science, clinical and regulatory strategy underlying Lisata's research and development programs, as well as associated staffing and budgets. It also reviews the interactions of the research and development organization with health care providers and regulatory bodies. The Science and Technology Committee met four times during the year.

Qualifications for Board Membership

The Nominating and Governance Committee Charter mandates that the Committee consider and recruit qualified candidates in consultation with the Company's President and Chief Executive Officer and affords the Committee the flexibility to determine the desired qualifications, expertise and characteristics most suited to the needs of the Lisata Board at any given time.

Diversity Considerations in Director Nominations

We do not have a formal diversity policy. We believe the Lisata Board represents a collection of individuals with a variety of complementary skills which, as a group, constitute the appropriate skills and experience to oversee Lisata's business. Our directors come from diverse backgrounds, including medicine, private equity, and management of pharmaceutical and healthcare-related companies. In accordance with the mission set out in its charter, our Nominating and Governance Committee considers a wide variety of qualifications, attributes and other factors and recognizes that a diversity of viewpoints and practical experiences can enhance the effectiveness of the Lisata Board. As part of its evaluation of each candidate, our Nominating and Governance Committee takes into account how that candidate's background, experience, qualifications, attributes and skills may complement, supplement or duplicate those of other directors or prospective candidates.

Nominating and Governance Committee Procedures

The Lisata Board generally believes that we are well-served by our current directors. In the ordinary course, absent special circumstances or a material change in the criteria for Board membership, the Lisata Board will re-nominate incumbent directors who continue to be qualified for Board service and are willing to continue as directors. If an incumbent director is not standing for re-election or is not re-nominated if a vacancy on the Lisata Board occurs between annual stockholder meetings or

if the Lisata Board believes it is in our best interests to expand its size, the Lisata Board may seek out potential candidates for Lisata Board appointment who meet the criteria for selection as a nominee and have the specific qualities or skills being sought. Nominees for director must be discussed by the full Board and approved for nomination by the affirmative vote of a majority of the Lisata Board, including the affirmative vote of a majority of the independent directors.

The Nominating and Governance Committee assists the Lisata Board by identifying qualified candidates for director and recommends to the Lisata Board the director nominees for the annual meeting of stockholders. The Lisata Board will conduct a process of making a preliminary assessment of each proposed nominee based upon the nominee's resume and biographical information, an indication of the individual's willingness to serve and other background information. This information is evaluated against specific needs at that time. Based upon a preliminary assessment of the candidate(s), those who appear best suited to meet our needs may be invited to participate in a series of interviews, which are used as a further means of evaluating potential candidates. Based on information learned during this process, the Lisata Board will determine which nominee(s) to include in the slate of candidates that the Lisata Board recommends for election at each annual meeting of our stockholders.

Procedures for Considering Nominations Made by Stockholders

The procedures for stockholders submitting nominating recommendations described in our By-laws detail the procedures for nominations to be submitted by stockholders, other than candidates who have previously served on the Lisata Board or who are recommended by the Lisata Board. Our By-laws state that: "For any nomination or other business proposal to be properly brought before an Annual Meeting by a stockholder pursuant to clause (iii) of Article I, Section 1.10(A)(1) of these By-laws, the stockholder must (i) have given Timely Notice (as defined below) thereof in writing to the Assistant Corporate Secretary of the Corporation, (ii) have provided any updates or supplements to such notice at the times and in the forms required by these By-laws and, (iii) together with the beneficial owner(s), if any, on whose behalf the nomination or other business proposal is made, have acted in accordance with the representations set forth in the Solicitation Statement (as defined below) required by these By-laws. To be timely, a stockholder's written notice shall be received by the Assistant Corporate Secretary at the principal executive offices of the Corporation not later than the close of business on the one hundred and twentieth (120th) day nor earlier than the close of business on the one hundred fiftieth (150th) day prior to the one-year anniversary of the preceding year's Annual Meeting date; provided that, in the event the Annual Meeting is first convened more than thirty (30) days before or more than sixty (60) days after the one-year anniversary of the preceding year's Annual Meeting date, or if no Annual Meeting was held in the preceding year, notice by the stockholder to be timely must be received by the Assistant Corporate Secretary of the Corporation not later than the close of business on the later of the ninetieth (90th) day prior to the scheduled date of such Annual Meeting or the tenth (10th) day following the day on which public announcement of the date of such meeting is first made (such notice within such time periods shall be referred to as "Timely Notice")."

There will be no differences in the manner in which the Lisata Board evaluates nominees recommended by stockholders and nominees recommended by the Lisata Board or management, except that no specific process shall be mandated with respect to the nomination of any individuals who have previously served on the Lisata Board.

Stockholder Communications

The Lisata Board has established a procedure that enables stockholders to communicate in writing with members of the Lisata Board. Any such communication should be addressed to our Assistant Corporate Secretary and should be sent to such individual c/o Lisata Therapeutics, Inc., P.O. Box 173, Liberty Corner, NJ 07938. Any such communication must state, in a conspicuous manner, that it is intended for distribution to the entire Board. Under the procedures established by the Lisata Board, upon our Assistant Corporate Secretary's receipt of such a communication, a copy of such communication will be sent to each member of the Lisata Board, identifying it as a communication received from a stockholder. Absent unusual circumstances, at the next regularly scheduled meeting of the Lisata Board held more than two days after such communication has been distributed, the Lisata Board will consider the substance of any such communication.

Board and Committee Meeting Attendance

During the year ended December 31, 2025, the Lisata Board held ten meetings, the Audit Committee held five meetings, the Compensation Committee held six meetings, the Nominating and Governance Committee held four meetings and the Science and Technology Committee held four meetings. The Lisata Board took additional actions by written consent. Each director attended (or participated by telephone) in 100% of the total number of meetings of the Lisata Board and committees on which he or she served, with the exception of one Audit Committee meeting, one Nominating and Governance Committee meeting and two Board meetings for which one member was absent.

Director Attendance at Annual Stockholder Meetings

We do not have a formal policy regarding attendance by directors at our annual meetings of stockholders but invite and encourage all directors to attend. We make every effort to schedule our annual meeting of stockholders at a time and date to permit attendance by directors, taking into account the directors' schedules and the timing requirements of applicable law. We have converted to a virtual meeting format for our annual meeting, which we have found it to be beneficial in that it allows more stockholders the possibility of participating and, thus, allowing us to reach a greater number of our stockholders. All then-current Board members attended the Company's virtual annual meeting in 2025.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires Lisata's directors, certain officers of Lisata, and persons who beneficially own more than 10% of a registered class of Lisata's equity securities, to file initial reports of ownership and reports of changes in ownership with the SEC. These persons are required by the SEC to furnish Lisata with copies of all Section 16(a) reports that they file.

Based solely on a review of Forms 3 and 4 and amendments thereto furnished to Lisata during 2025, filed by our officers, directors, and any person whom we understand to own more than 10% of our common stock, all Section 16(a) filings were timely filed to our knowledge.

Code of Ethics

We have adopted a code of ethics that applies to our directors, officers and employees, except to our President and Chief Executive Officer, principal financial officer, principal accounting officer, controller, or persons performing similar functions, who are subject to a separate code of ethics. Both codes of ethics are available on our website, www.lisata.com.

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth the total compensation paid or accrued during the last two fiscal years with respect to (i) our President and Chief Executive Officer, (ii) our two other most highly compensated executive officers, who each earned more than \$100,000 during the fiscal year ended December 31, 2025, and were serving as executive officers as of such date (our “Named Executive Officers”).

Name and Principal Position	Year	Salary	Bonus	Stock Awards (1)	Option Awards (1)	All Other Compensation	Total Compensation
David J. Mazzo, President and Chief Executive Officer	2025	\$711,729	\$ —	\$ 307,800	\$ 104,080	\$ 23,750 ⁽²⁾	\$ 1,147,359
	2024	\$702,969	\$ 387,876	\$ 468,160 ⁽³⁾	\$ 101,920	\$ 30,250 ⁽⁴⁾	\$ 1,691,174
Kristen K. Buck, M.D., Executive Vice President R&D and Chief Medical Officer	2025	\$599,342	\$ —	\$ 95,000	\$ 33,826	\$ 8,250 ⁽⁵⁾	\$ 736,418
	2024	\$597,421	\$ 299,671	\$ 129,360 ⁽⁶⁾	\$ 30,359	\$ 8,250 ⁽⁷⁾	\$ 1,065,061
James Nisco, Senior Vice President, Finance and Treasury and Chief Accounting Officer	2025	\$350,000	\$ —	\$ 57,000	\$ 18,214	\$ 8,250 ⁽⁸⁾	\$ 433,464
	2024	\$341,938	\$ 122,500	\$ 34,804 ⁽⁹⁾	\$ 8,674	\$ 8,250 ⁽¹⁰⁾	\$ 516,166

- (1) Amounts shown under “Stock Awards” and “Option Awards” represent the aggregate grant date fair value computed in accordance with FASB ASC Topic 718, in accordance with SEC rules. See Note 9 to the Notes to the Consolidated Financial Statements in our 2025 Form 10-K, for a discussion of assumptions made in such valuations. All stock awards, option awards and other shares discussed in this table were issued under the 2018 Plan, with a per share price generally equal to the fair market value of a share of our common stock on the date of grant.
- (2) Consisted of (i) a car allowance of \$5,500, (ii) \$8,250 of Company 401(k) match, and (iii) a life and disability insurance allowance of \$10,000.
- (3) Includes the grant of 58,000 performance stock units with a grant date fair value of \$178,640, which is also the maximum potential value at the time of the grant. The performance criteria for the performance stock units were met in 2024.
- (4) Consisted of (i) a car allowance of \$12,000, (ii) \$8,250 of Company 401(k) match, and (iii) a life and disability insurance allowance of \$10,000.
- (5) Consisted of \$8,250 Company 401(k) match.
- (6) Includes the grant of 15,000 performance stock units with a grant date fair value of \$46,200, which is also the maximum potential value at the time of the grant. The performance criteria for the performance stock units were met in 2024.
- (7) Consisted of \$8,250 Company 401(k) match.
- (8) Consisted of \$8,250 Company 401(k) match.
- (9) Includes the grant of 3,300 performance stock units with a grant date fair value of \$10,164, which is also the maximum potential value at the time of the grant. The performance criteria for the performance stock units were met in 2024.
- (10) Consisted of \$8,250 Company 401(k) match.

LISATA EMPLOYMENT AGREEMENTS AND EQUITY GRANTS

Employment Agreements and Other Arrangements with Executive Officers

This section contains a description of the employment agreements and certain other arrangements that Lisata has or had during the years ended December 31, 2025 and December 31, 2024, with the Named Executive Officers listed in the Summary Compensation Table. All descriptions are qualified in their entirety by reference to such agreements. The descriptions to follow provide further information about the compensation that is shown in the Summary Compensation Table for the respective officers. They also provide information about payments that could be received by these officers under certain circumstances at such time as their employment with Lisata ends, for example, certain severance arrangements.

David J. Mazzo, Ph.D. - President and Chief Executive Officer

In connection with his appointment as the Company's President and Chief Executive Officer, Dr. Mazzo and the Company entered into an Amended and Restated Employment Agreement dated and effective as of March 19, 2021, (the "Mazzo Agreement"). Under the terms of the Mazzo Agreement, Dr. Mazzo will continue to perform his duties as the Company's President and Chief Executive Officer at an annual base salary of \$705,229, subject to review and increase by the Board and/or Compensation Committee. Dr. Mazzo received an annual base salary of \$711,729 in 2025 and \$702,969 in 2024. He is also eligible for an annual bonus (short-term incentive) with a target of 55% of his then-current base salary and a maximum of 100% of his then-current base salary, as determined by the Compensation Committee based on his performance for the respective year. Dr. Mazzo received an annual bonus of \$387,876 in 2024. He did not receive a bonus in 2025. Subject to earlier termination in accordance with the terms of the Mazzo Agreement, the term of Dr. Mazzo's employment is one year, which is automatically extended for successive one-year periods unless the Company provides Dr. Mazzo with written notice of termination at least 90 days' prior to the end of the then-current term. The Agreement also provides Dr. Mazzo with the option to terminate his employment with the Company if: (i) the Company materially breaches its obligations under the Mazzo Agreement, (ii) the Company materially reduces Dr. Mazzo's position, duties, responsibilities or authority or repeatedly assigns Dr. Mazzo duties that are materially inconsistent with those set forth in the Mazzo Agreement, in either case without Dr. Mazzo's consent, (iii) the Company relocates Dr. Mazzo's principal place of employment, without Dr. Mazzo's consent, in a manner than lengthens his one-way commute distance by fifty (50) miles or more, and/or (iv) Dr. Mazzo provides the Company with thirty (30) days' prior written notice.

The Mazzo Agreement provides Dr. Mazzo with certain benefits, including but not limited to: (i) twenty-nine (29) days paid time off, (ii) up to \$10,000 annually for supplemental term life insurance coverage and supplemental long-term disability coverage, and (iii) a non-accountable annual expense allowance of \$12,000.

Pursuant to the Mazzo Agreement, Dr. Mazzo is entitled to receive certain payments following his termination. If Dr. Mazzo resigns for Good Reason (as defined below) or is terminated by the Company without Cause (as defined below), then he will be entitled to receive (i) a lump sum payment equal to the sum of any earned but unpaid base salary, any earned and vested but unpaid bonus amounts, any accrued and unused paid time off, any unreimbursed business expenses or other amounts due, and any other payments or benefits to which Dr. Mazzo may then be entitled under the terms of any compensation arrangement with the Company (the "Mazzo Accrued Payments"); (ii) severance payments (the "Mazzo Salary Payments") equal to Dr. Mazzo's then-current base salary for a period of 15 months following termination (the "Mazzo Severance Period"); (iii) COBRA assistance for the duration of the Mazzo Severance Period, not including the portion of the monthly premium which Dr. Mazzo would otherwise have paid if he had not resigned or been terminated (the "Mazzo COBRA Payments") and (iv) a bonus payment equal to 125% of 55% of Dr. Mazzo's then-effective base salary, paid in equal installments for the duration of the Mazzo Severance Period (the "Mazzo Bonus Payment," and together with the Mazzo Accrued Payments, the Mazzo Severance Payments and the Mazzo COBRA Payments, the "Mazzo Severance Payments"). Payment of the Mazzo Salary Payments, the Mazzo COBRA Payments and the Mazzo Bonus Payment will be made subject to execution of a release of claims by Dr. Mazzo. Additionally, if Dr. Mazzo resigns for Good Reason or is terminated without Cause and executes a release of claims, 25% of his outstanding unvested equity awards shall immediately fully vest and be exercisable for one year following termination or the remaining term of such awards, whichever period is shorter. Finally, if Dr. Mazzo resigns for Good Reason or is terminated without Cause during any period commencing on the effective date of a Change in Control (as defined below) and ending on the second anniversary of such effective date (a "Mazzo Change of Control Period"), subject to his execution of a release of claims, Dr. Mazzo will be entitled to receive the Mazzo Severance Payments with the following adjustments: (i) the Mazzo Severance Period will be extended from 15 months to 18 months, (ii) the Mazzo COBRA Payments shall be increased to cover the entire monthly premium for such coverage and (iii) the Mazzo Bonus Payment will equal 150% of Dr. Mazzo's then-current target bonus. Further, if Dr. Mazzo resigns for Good Reason or is terminated without Cause during a Change of Mazzo Control Period, 100% of his outstanding unvested equity awards shall immediately fully vest and be exercisable for one year following termination or the remaining term of such awards, whichever period is shorter. If Dr. Mazzo resigns without Good Reason or is terminated for Cause, then he shall be entitled only to the Mazzo Accrued Payments. If Dr. Mazzo is terminated upon his death or disability, then he (or his estate, as applicable) shall be entitled to receive the Mazzo Accrued Payments and, subject to a release of claims, the Mazzo COBRA Payments.

On June 10, 2025, the Company entered into an amended and restated employment agreement with David J. Mazzo, Ph.D., the Company's Chief Executive Officer (the "Mazzo Second Amended and Restated Employment Agreement"). The Mazzo Second Amended and Restated Employment Agreement supplements and amends the Amended and Restated Employment Agreement, dated and effective as of March 19, 2021, between Dr. Mazzo and the Company.

The Mazzo Second Amended and Restated Employment Agreement: (i) amended Dr. Mazzo's base salary to \$717,229 from \$633,032 and removed the non-accountable expense allowance of \$12,000 per year, (ii) clarified that a material reduction in Dr. Mazzo's base salary is included in the definition of "Good Reason", (iii) amended that in the event of Dr. Mazzo's termination from the Company within two years following a Change in Control (as defined therein), any determination on (a) whether Dr. Mazzo's termination constitutes a termination with or without Cause (as defined therein) or with or without Good Reason (as defined therein) and (b) Dr. Mazzo's entitlement to the separation benefits and payments described therein, will be determined by the board of directors of the Company as constituted immediately prior to such Change in Control, which board may delegate its authority to a qualified independent third party, (iv) amended Dr. Mazzo's COBRA benefit coverage after the date of termination to monthly reimbursement payments for the cost of Dr. Mazzo's group health plan coverage, except in the event that such payment would incur tax penalties to the Company, violate applicable nondiscrimination requirements or in the event that the Company terminates the group health plan, in which case the Company will pay Dr. Mazzo a lump-sum cash payment equal to the aggregate cost of the remaining reimbursement payments less required withholdings, (v) amends the form of payment of Dr. Mazzo's bonus payments in the event of a termination not in connection to a Change in Control to a lump-sum payment, (vi) amended the definition of "Change in Control" therein to include the approval by the shareholders of the Company of any plan of complete liquidation of the Company, provided that the Change in Control meets all of the requirements of a "change in control" within the meaning of Treasury Regulation §1.409A-3(i)(5), (vii) clarified that the base salary severance payments, to the extent that the payments are in the aggregate less than or equal to twice the compensation limit under Section 401(a)(17) of the Internal Revenue Code of 1986, as amended (the "Code"), comply with the involuntary separation pay plan exception to Section 409A of the Code, and further clarified that Dr. Mazzo may receive such severance payments as a lump sum payment on the next payroll period following the date of his termination from employment; and (viii) clarified other technical terms for compliance with Section 409A of the Code.

On January 9, 2024, pursuant to the Mazzo Agreement, Dr. Mazzo was granted an option to purchase 47,000 shares of common stock at an exercise price of \$3.08 per share and (ii) 94,000 restricted stock awards granted under the Issuer's 2018 Equity Incentive Compensation Plan. In addition, on January 9, 2024, Dr. Mazzo was granted 58,000 performance-based stock units.

On January 9, 2025, pursuant to the Mazzo Agreement, Dr. Mazzo was granted an option to purchase 40,000 shares of common stock at an exercise price of \$3.80 per share and (ii) 81,000 restricted stock awards granted under the Issuer's 2018 Equity Incentive Compensation Plan.

Kristen K. Buck, M.D. - Executive Vice President R&D and Chief Medical Officer

In connection with her appointment as Executive Vice President, R&D and Chief Medical Officer, Dr. Buck and the Company entered into an Employment Agreement dated and effective as of July 26, 2021 (the "Buck Agreement"), setting forth the terms and conditions of Dr. Buck's employment with the Company. Under the terms of the Buck Agreement, Dr. Buck is entitled to receive an annual base salary of \$599,342, which is subject to adjustment based on the discretion of the Compensation Committee of the Lisata Board of Directors. Dr. Buck received an annual base salary of \$599,342 in 2025 and \$597,421 in 2024. The Buck Agreement had an initial term expiring on September 1, 2024, which has been and shall continue to be automatically extended for additional one-year periods unless Dr. Buck is provided written notice by the Company no later than ninety (90) days prior to the expiration of the initial term. In connection with her hire, Dr. Buck was granted options to purchase \$1,000,000 of common stock and restricted stock awards with a value of \$400,000, both of which vested in three equal annual installments starting on September 1, 2021, in addition to an annual bonus (short-term incentive) with a target of 50% of her then-current base salary as determined by the Compensation Committee based on her performance for the respective year. Dr. Buck received an annual bonus of \$299,671 in 2024. She did not receive a bonus in 2025.

On January 9, 2024, pursuant to the Buck Agreement, Dr. Buck was granted an option to purchase 14,000 shares of common stock at an exercise price of \$3.08 per share and (ii) 27,000 restricted stock awards granted under the Issuer's 2018 Equity Incentive Compensation Plan. In addition, on January 9, 2024, Dr. Buck was granted 15,000 performance-based stock units.

On January 9, 2025, pursuant to the Buck Agreement, Dr. Buck was granted an option to purchase 13,000 shares of common stock at an exercise price of \$3.80 per share and (ii) 25,000 restricted stock awards granted under the Issuer's 2018 Equity Incentive Compensation Plan.

The Buck Agreement provides Dr. Buck with certain benefits, including but not limited to twenty-nine (29) days paid time off.

Pursuant to the Buck Agreement, Dr. Buck is entitled to receive certain payments following her termination. If Dr. Buck resigns for Good Reason (as defined below) or is terminated by the Company without Cause (as defined below), then she will be entitled to receive (i) a lump sum payment equal to the sum of any earned but unpaid base salary, any earned and vested but unpaid bonus amounts, any accrued and unused paid time off, any unreimbursed business expenses or other amounts due, and any other payments or benefits to which Dr. Buck may then be entitled under the terms of any compensation arrangement with the Company (the “Buck Accrued Payments”); (ii) severance payments (the “Buck Salary Payments”) equal to Dr. Buck’s then-current base salary for a period of 12 months following termination (the “Buck Severance Period”); (iii) COBRA assistance for the duration of the Buck Severance Period, not including the portion of the monthly premium which Dr. Buck would otherwise have paid if she had not resigned or been terminated (the “Buck COBRA Payments”) and (iv) a bonus payment equal to 50% of Dr. Buck’s then-effective base salary, paid in equal installments for the duration of the Buck Severance Period (the “Buck Bonus Payment,” and together with the Buck Accrued Payments, the Buck Severance Payments and the Buck COBRA Payments, the “Buck Severance Payments”). Payment of the Buck Salary Payments, the Buck COBRA Payments and the Buck Bonus Payment will be made subject to execution of a release of claims by Dr. Buck. Additionally, if Dr. Buck resigns for Good Reason or is terminated without Cause and executes a release of claims, the exercise period of her vested option awards shall be extended to one year following termination or the remaining term of such awards, whichever period is shorter. Finally, if Dr. Buck resigns for Good Reason or is terminated without Cause during any period commencing on the effective date of a Change in Control (as defined below) and ending on the first anniversary of such effective date (a “Buck Change of Control Period”), subject to her execution of a release of claims, Dr. Buck will be entitled to receive the Buck Severance Payments with the following adjustments: (i) the Buck Severance Period will be extended from 12 months to 15 months, (ii) the Buck COBRA Payments shall be increased to cover the entire monthly premium for such coverage and (iii) the Buck Bonus Payment will equal 125% of 50% of Dr. Buck’s then-current base salary. Further, if Dr. Buck resigns for Good Reason or is terminated without Cause during a Buck Change of Control Period, 100% of her outstanding unvested equity awards shall immediately fully vest and be exercisable for one year following termination or the remaining term of such awards, whichever period is shorter.

If Dr. Buck resigns without Good Reason or is terminated for Cause, then she shall be entitled only to the Buck Accrued Payments. If Dr. Buck is terminated upon her death or disability, then she (or her estate, as applicable) shall be entitled to receive the Buck Accrued Payments and, subject to a release of claims, the Buck COBRA Payments.

On June 10, 2025, the Company entered into an amended and restated employment agreement with Kristen K. Buck, M.D., the Company’s Vice President, R&D and Chief Medical Officer (the “Buck Amended and Restated Employment Agreement”). The Buck Amended and Restated Employment Agreement supplemented and amended the Employment Agreement, dated and effective as of July 26, 2021, between Dr. Buck and the Company.

The Buck Amended and Restated Employment Agreement: (i) amended Dr. Buck’s base salary to \$599,342 from \$550,000, (ii) clarified that a material reduction in Dr. Buck’s base salary is included in the definition of “Good Reason”, (iii) amended that in the event of Dr. Buck’s termination from the Company within two years following a Change in Control (as defined therein), any determination on (a) whether Dr. Buck’s termination constitutes a termination with or without Cause (as defined therein) or with or without Good Reason (as defined therein) and (b) Dr. Buck’s entitlement to the separation benefits and payments described therein, will be determined by the board of directors of the Company as constituted immediately prior to such Change in Control, which board may delegate its authority to a qualified independent third party, (iv) amended Dr. Buck’s COBRA benefit coverage after the date of termination to monthly reimbursement payments for the cost of Dr. Buck’s group health plan coverage, except in the event that such payment would incur tax penalties to the Company, violate applicable nondiscrimination requirements or in the event that the Company terminates the group health plan, in which case the Company will pay Dr. Buck a lump-sum cash payment equal to the aggregate cost of the remaining reimbursement payments less required withholdings, (v) amended Dr. Buck’s bonus payments in the event of a termination not in connection to a Change in Control such that the amount will not be pro-rated for the number of days Dr. Buck was employed in the year of termination of employment, (vi) amended the definition of “Change in Control” therein to include the approval by the shareholders of the Company of any plan of complete liquidation of the Company, provided that the Change in Control meets all of the requirements of a “change in control” within the meaning of Treasury Regulation §1.409A-3(i)(5), (vii) clarifies that the base salary severance payments, to the extent that the payments are in the aggregate less than or equal to twice the compensation limit under Section 401(a)(17) of the Code comply with the involuntary separation pay plan exception to Section 409A of the Code, and further clarified that Dr. Buck may receive such severance payments as a lump sum payment on the next payroll period following the date of her termination from employment; and (viii) clarified other technical terms for compliance with Section 409A of the Code.

James Nisco - Senior Vice President Finance and Treasury and Chief Accounting Officer

Mr. Nisco is entitled to receive an annual base salary of \$350,000, which is subject to adjustment based on the discretion of the Compensation Committee of the Lisata Board of Directors. Mr. Nisco received an annual base salary of \$350,000 in 2025 and \$341,938 in 2024. In connection with his appointment to the position of Senior Vice President Finance and Treasury and Chief Accounting Officer, Mr. Nisco was granted an annual bonus (short-term incentive) with a target of 35% of his then-current base salary as determined by the Compensation Committee based on his performance for the respective year. Mr. Nisco is also entitled to receive stock awards annually. Mr. Nisco received an annual bonus of \$122,500 in 2024. He did not receive a bonus in 2025.

On January 9, 2024, Mr. Nisco was granted an option to purchase 4,000 shares of common stock at an exercise price of \$3.08 per share and (ii) 8,000 restricted stock awards granted under the Issuer's 2018 Equity Incentive Compensation Plan. In addition, on January 9, 2024, Mr. Nisco was granted 3,300 performance-based stock units.

On January 9, 2025, Mr. Nisco was granted an option to purchase 7,000 shares of common stock at an exercise price of \$3.80 per share and (ii) 15,000 restricted stock awards granted under the Issuer's 2018 Equity Incentive Compensation Plan.

Mr. Nisco and the Company entered into a letter agreement dated and effective as of September 12, 2016, and further revised on March 25, 2022 (the "Nisco Severance Agreement"). Pursuant to the Nisco Severance Agreement, Mr. Nisco is entitled to receive certain payments following his termination. If Mr. Nisco terminates his employment for Good Reason (as defined below) during the period commencing on the effective date of a Nisco Change in Control (as defined below) and ending on the second anniversary of the effective date of a Nisco Change in Control, or the Company terminates Mr. Nisco's employment without Cause (as defined below) (other than by reason of his death or disability), the Company will (a) continue to pay Mr. Nisco's current base salary of \$350,000 (the "Nisco Salary Payment") for 12 months following the date the termination becomes effective (the "Nisco Severance Period"), commencing on the next payroll period following the date the termination becomes effective and (b) pay Mr. Nisco a lump-sum equal to 100% of Mr. Nisco's then annual target bonus on the next payroll period following the date the termination becomes effective (the "Nisco Cash Severance") and (c) pay monthly the monthly premium amount for continued COBRA coverage. If the Company may not pay Mr. Nisco's COBRA premiums without incurring tax penalties or violating any requirement of law, the Company shall use its commercially reasonable best efforts to provide Mr. Nisco with substantially similar assistance in an alternative manner (the "Nisco COBRA Payments"), provided that the cost of doing so does not exceed the cost that the Company would have incurred had the Company been able to pay the COBRA premiums on Mr. Nisco's behalf. In addition to the Nisco Salary Payment, Nisco Cash Severance and the Nisco COBRA Payments, the Company shall (i) fully vest as of the date the termination becomes effective, all outstanding unvested equity awards, including options granted to Mr. Nisco; and (ii) extend the exercise date of the options to the earlier of the one-year anniversary of the date the termination becomes effective and the original expiration date of the options.

Additionally, Mr. Nisco and the Company entered into a non-change in control severance pay agreement (the "Nisco Separation Pay Agreement"), effective January 1, 2025. Pursuant to the Nisco Separation Pay Agreement, Mr. Nisco is entitled to receive the following payments, in exchange for his release of claims: (a) the Company will continue to pay Mr. Nisco's current base salary of \$350,000 for 12 months following the date the termination becomes effective, commencing on the next payroll period following the date the termination becomes effective, (b) the Company will pay a lump-sum equal to 100% of Mr. Nisco's then annual target bonus on the next payroll period following the date of his termination, (c) the Company will pay Mr. Nisco's accrued wages through the date of termination, including any accrued but untaken paid time off, (d) the Company will reimburse medical, dental and vision coverage through COBRA for a 12-month period following the date of termination, either via lump-sum payment or monthly, as mutually agreed and (e) the Company will extend the exercise date of any fully vested options to the earlier of the one-year anniversary of the date the termination becomes effective and the remaining term of the option award.

On June 10, 2025, the Company entered into an amended and restated separation benefits agreement with James Nisco, Senior Vice President Finance and Treasury and Chief Accounting Officer of the Company (the "Nisco Amendment"). The Nisco Amendment supplemented and amended the separation benefits provided in the Non-Change in Control Separation Pay Agreement between the Company and Mr. Nisco, dated as of December 24, 2024, and the severance agreement between Mr. Nisco and the Company, dated and effective as of September 12, 2016, and further amended on March 25, 2022.

The Nisco Amendment: (i) amended the definition of "Change in Control" therein to include the approval by the shareholders of the Company of any plan of complete liquidation of the Company, provided that the Change in Control meets all of the requirements of a "change in control" within the meaning of Treasury Regulation §1.409A-3(i)(5), (ii) included a condition that Mr. Nisco's right to the severance payments and benefits described therein are subject to Mr. Nisco's timely execution and non-revocation of a general release of claims within sixty days following Mr. Nisco's termination or such shorter time period set forth therein, (iii) amended Mr. Nisco's COBRA benefit coverage after the date of termination to monthly reimbursement payments for the cost of Mr. Nisco's group health plan coverage, except in the event that such payment would

incur tax penalties to the Company, violate applicable nondiscrimination requirements or in the event that the Company terminates the group health plan, in which case the Company will pay Mr. Nisco a lump-sum cash payment equal to the aggregate cost of the remaining reimbursement payments less required withholdings, (iv) amended that in the event of Mr. Nisco's termination from the Company within two years following a Change in Control (as defined therein), any determination on (a) whether Mr. Nisco's termination constitutes a termination with or without Cause (as defined therein) or with or without Good Reason (as defined therein) and (b) Mr. Nisco's entitlement to the separation benefits and payments described therein, will be determined by the board of directors of the Company as constituted immediately prior to such Change in Control, which board may delegate its authority to a qualified independent third party, (v) clarified that the base salary severance payments, to the extent that the payments are in the aggregate less than or equal to twice the compensation limit under Section 401(a)(17) of the Code, comply with the involuntary separation pay plan exception to Section 409A of the Code, and further clarifies that Mr. Nisco may receive such severance payments as a lump sum payment on the next payroll period following the date of his termination from employment; and (vi) clarified other technical terms for compliance with Section 409A of the Code.

Employment Agreements – Common Definitions

The following definitions apply to each of the Mazzo Agreement and the Buck Agreement:

“Cause” means that, as determined by the Board, the executive has (A) committed gross negligence in connection with the executive's duties as set forth in the applicable employment agreement or otherwise with respect to the business and affairs of the Company, its subsidiaries and/or its other affiliates; (B) committed fraud in connection with his or duties as set forth in the applicable employment agreement or otherwise with respect to the business and affairs of the Company, its subsidiaries and/or its other affiliates; (C) engaged in personal dishonesty, willful misconduct, willful violation of any law, or breach of fiduciary duty, in each instance, with respect to the business and affairs of the Company, its subsidiaries and/or its other affiliates; (D) been indicted for or has been found by a court of competent jurisdiction to have committed or plead guilty to (1) a felony (or state law equivalent) or (2) any other serious crime involving moral turpitude or that has (or is reasonably likely to have) a material adverse effect either on (x) the executive's ability to perform his or her duties under the applicable employment agreement or (y) the reputation and goodwill of the Company, regardless of whether or not such other crime is related or unrelated to the business of the Company, its subsidiaries or other affiliates; (E) shown chronic use of alcohol, drugs or other similar substances that materially affects the executive's work performance; (F) breached his or her obligations under (1) the applicable employment agreement, (2) the Confidentiality and Inventions Assignment Agreement attached to the applicable employment agreement, or (3) any other agreement executed by the executive for the benefit of the Company, its subsidiaries and/or other affiliates, provided, that, if such breach described in this clause (F) is susceptible to cure (as determined in the reasonable discretion of the Board), the executive shall have thirty (30) days after notice from the Board to cure such breach; or (G) failed to materially perform the executive's duties or to follow the lawful directives of the Board; provided, that, if such failure described in this clause (G) is susceptible to cure (as determined in the reasonable discretion of the Board), the executive shall have thirty (30) days after notice from the Board to cure such failure; or (H) materially violated the Company's written code of conduct or other written or established policies and/or procedures in place from time to time; provided, that, if such violation described in this clause (H) is susceptible to cure (as determined in the reasonable discretion of the Board), the executive shall have thirty (30) days after notice from the Board to cure such violation.

“Good Reason” means the occurrence of any of the following events: (A) material breach by the Company of its obligations under the applicable employment agreement; (B) the executive's position, duties, responsibilities, or authority have been materially reduced or the executive has repeatedly been assigned duties that are materially inconsistent with his duties set forth herein, in each case, without the executive's consent or (C) the relocation of the executive's principal place of employment, without the executive's consent, in a manner that lengthens his one-way commute distance by 50 or more miles. Notwithstanding the foregoing, however, “Good Reason” shall not be deemed to exist unless (1) the executive shall have given written notice to the Company specifying in reasonable detail the Company's acts or omissions that the executive alleges constitute “Good Reason” within 60 days after the first occurrence of such circumstances and the Company shall have failed to cure any such act or omission within 60 days of receipt of such written notice, and (2) the executive actually terminates employment within 180 days following the initial occurrence of any of the foregoing conditions that he or she considers to be “Good Reason.”

“Change in Control” means a transaction or a series of related transactions in which the assets of the Company are transferred to any “person” or “group” (as such terms are defined in Section 13(d)(3) and 14(d)(2) of the Exchange Act); (x) any person or group becomes the “beneficial owner” (as defined in Rules 13d-3 and 13d-5 under the Exchange Act), directly or indirectly, of the Company's outstanding equity representing more than 30% of the total voting power of the Company's then-outstanding equity; (y) the Company undergoes a merger, reorganization or other consolidation in which the holders of the outstanding equity of the Company immediately prior to such merger, reorganization or consolidation own less than 50% of the surviving entity's voting power immediately after the transaction; or (z) the date a majority of the members of the incumbent Board is replaced during any twelve month period by members whose appointment or election is not endorsed by a majority to

the incumbent Board before the date of the appointment or election, provided further that the Change in Control meets all of the requirements of a "change in the ownership of a corporation" within the meaning of Treasury Regulation §1.409A-3(i)(5)(vi), a "change in the effective ownership of a corporation" within the meaning of Treasury Regulation §1.409A-3(i)(5)(vi), or "a change in the ownership of a substantial portion of the corporation's assets" within in the meaning of Treasury Regulation §1.409A-3(i)(5)(vii). For purposes of (z), the incumbent directors of the Board includes the members of the Board as of the date of the applicable employment agreement and any additional or replacement director appointed or elected whose election or appointment is endorsed or approved by a majority of the incumbent Board.

The following definitions apply to the Nisco Severance Agreement except as described above regarding the Nisco Amendment:

"Cause" means that, as determined by the Company's Board of Directors, the executive has: (i) committed gross negligence in connection with the executive's duties or otherwise with respect to the business and affairs of the Company, its subsidiaries and/or its other affiliates; (ii) committed fraud in connection with the executive's duties or otherwise with respect to the business and affairs of the Company, its subsidiaries and/or its other affiliates; (iii) engaged in personal dishonesty, willful misconduct, willful violation of any law, or breach of fiduciary duty, in each instance, with respect to the business and affairs of the Company, its subsidiaries and/or its other affiliates; (iv) been indicted for, or has been found by a court of competent jurisdiction to have committed or pled guilty to, (A) a felony (or state law equivalent) or (B) any other serious crime involving moral turpitude or that has (or is reasonably likely to have) a material adverse effect either on (x) the executive's ability to perform the executive's duties for the Company or (y) the reputation and goodwill of the Company, regardless of whether or not such other crime is related or unrelated to the business of the Company, its subsidiaries or other affiliates; (v) shown chronic use of alcohol, drugs or other similar substances that materially affects the executive's work performance; (vi) breached the executive's obligations under any written agreement between the executive and the Company related to confidentiality, non-competition, non-solicitation or the assignment of intellectual property; (vii) failed to materially perform the executive's duties or to follow the lawful directives of the Board of Directors: provided, that if such failure described in this clause (vii) is susceptible to cure (as determined in the reasonable discretion of the Board of Directors), the executive shall have thirty (30) days after notice from the Board of Directors to cure such failure; or (viii) materially violated the Company's written code of conduct or other written or established policies and/or procedures in place from time to time; provided, that if such violation described in this clause (viii) is susceptible to cure (as determined in the reasonable discretion of the Board of Directors), the executive shall have thirty (30) days after notice from the Board of Directors to cure such violation. Any notice to the executive under this clause shall be in writing and shall specify in reasonable detail the executive's acts or omissions that the Company alleges constitute "Cause."

"Change in Control" means a transaction or a series of related transactions in which: (i) all or substantially all of the assets of the Company are transferred to any "person" or "group" (as such terms are defined in Section 13(d)(3) and 14(d)(2) of the Exchange Act); (ii) any person or group becomes the "beneficial owner" (as defined in Rules 13d-3 and 13d-5 under the Exchange Act), directly or indirectly, of the Company's outstanding equity representing more than 30% of the total voting power of the Company's then-outstanding equity; (iii) the Company undergoes a merger, reorganization or other consolidation in which the holders of the outstanding equity of the Company immediately prior to such merger, reorganization or consolidation own less than 50% of the surviving entity's voting power immediately after the transaction; or (iv) the date a majority of the members of the Company's incumbent Board of Directors is replaced during any twelve month period by members whose appointment or election is not endorsed by a majority to the Company's incumbent Board of Directors before the date of the appointment or election, provided further that the Change in Control meets all of the requirements of a "change in the ownership of a corporation" within the meaning of Treasury Regulation §1.409A-3(i)(S)(v), a "change in the effective ownership of a corporation" within the meaning of Treasury Regulation §1.409A-3(i)(5)(vi), or "a change in the ownership of a substantial portion of the corporation's assets" within in the meaning of Treasury Regulation §1.409A-3(i)(S)(vii). For purposes of (z), the incumbent Directors of the Board of Directors includes the members of the Board of Directors as of the date of this Agreement and any additional or replacement Director appointed or elected who is endorsed by a majority of the Company's incumbent Board of Directors."

"Good Reason" means (i) a material reduction in the executive's base salary; (ii) the executive's position, duties, responsibilities, or authority have been materially reduced or the executive has been repeatedly assigned duties that are materially inconsistent with the executive's duties, in each case, without the executive's consent; or (iii) the requirement that the executive relocate the executive's primary place of employment more than 50 miles from the executive's current place of employment (unless such location is closer to the executive's primary residence). "Good Reason" shall not be deemed to exist, however, unless (x) the executive shall have given written notice to the Company specifying in reasonable detail the Company's acts or omissions that the executive alleges constitute "Good Reason" within sixty (60) days after the first occurrence of such circumstances and the Company shall have failed to cure any such act or omission within sixty (60) days of receipt of such written notice, and (y) the executive actually terminates the executive's employment within one hundred eighty (180) days following the initial occurrence of the condition the executive considers to be "Good Reason." If the executive fails to provide

this notice and cure period prior to the executive's resignation or resign more than one hundred eighty (180) days after the initial existence of the condition, the executive's resignation will not be deemed to be for "Good Reason."

Indemnification Agreements

We enter into indemnification agreements with each of our executive officers and each of our directors from time to time pursuant to which we have agreed to indemnify such party to the full extent permitted by law, subject to certain exceptions, if such party becomes subject to an action because such party is our director, officer, employee, agent or fiduciary.

Acceleration of Vesting Under Equity Compensation Plans

Generally, in the event of a Change in Control of Lisata (as defined in the 2009 Plan, the 2015 Plan and the 2018 Plan) and either (i) the failure of Lisata's successor to assume a participant's awards or (ii) such assumption of awards is followed by the participant's termination without cause on or within the one-year period following the Change in Control, (a) all outstanding options and stock appreciation rights of each participant granted prior to the change in control shall be fully vested and immediately exercisable in their entirety, and (b) all unvested stock awards, restricted stock units, restricted stock, performance-based awards, and other awards shall become fully vested, including without limitation, the following: (i) the restrictions to which any shares of restricted stock granted prior to the change in control are subject shall lapse as if the applicable restriction period had ended upon such change in control, and (ii) the conditions required for vesting of any unvested performance-based awards shall be deemed to be satisfied upon such change in control.

Termination or Change in Control Payments

The following table sets forth aggregate estimated payment obligations to each of the Named Executive Officers assuming a termination occurred on December 31, 2025 under the circumstances specified below:

Name	Benefit	Before Change in Control	After Change in Control	Voluntary Termination
		Termination w/o Cause or for Good Reason (\$)	Termination w/o Cause or for Good Reason (\$)	
David J. Mazzo	Severance	1,389,631	1,667,557	—
	Health Benefits	53,320	63,984	—
	Equity Award Acceleration	—	228,315	—
	Total	1,442,951	1,959,856	—
Kristen Buck	Severance	899,013	1,123,766	—
	Health Benefits	20,792	25,990	—
	Equity Award Acceleration	—	68,355	—
	Total	919,805	1,218,111	—
James Nisco	Severance	472,500	472,500	—
	Health Benefits	54,550	54,550	—
	Equity Award Acceleration	—	30,921	—
	Total	527,050	557,970	—

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

The following table sets forth information on equity awards outstanding at December 31, 2025 for each of the Named Executive Officers.

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price**	Option Expiration Date	Number of shares or units of stock that have not vested (#)	Market value of shares or units of stock that have not vested \$(***)
David J. Mazzo	2,333 (1)	—	\$94.50	1/25/2026		
	3,394 (2)	—	\$71.55	9/29/2026		
	3,333 (3)	—	\$53.10	1/9/2027		
	3,333 (4)	—	\$56.85	1/8/2028		
	4,733 (5)	—	\$74.25	1/14/2029		
	4,600 (6)	—	\$49.20	1/13/2030		
	4,000 (7)	—	\$23.85	1/11/2031		
	13,333 (8)	—	\$13.76	1/10/2032		
	22,500 (9)	7,500 (9)	\$3.00	1/9/2033		
	23,500 (10)	23,500 (10)	\$3.08	1/9/2034		
	10,000 (11)	30,000 (11)	\$3.80	1/9/2035		
					15,000 (12)	\$27,900 (12)
					47,000 (13)	\$87,420 (13)
					60,750 (14)	\$112,995 (14)
Kristen Buck	75,861 (15)	—	\$19.20	9/1/2031		
	2,166 (16)	—	\$13.76	1/10/2032		
	6,750 (17)	2,250 (17)	\$3.00	1/9/2033		
	7,000 (18)	7,000 (18)	\$3.08	1/9/2034		
	3,250 (19)	9,750 (19)	\$3.80	1/9/2035		
					4,500 (20)	\$8,370 (20)
					13,500 (21)	\$25,110 (21)
					18,750 (22)	\$34,875 (22)
James Nisco	33 (23)	—	\$94.50	1/25/2026		
	398 (24)	—	\$71.55	9/29/2026		
	39 (25)	—	\$53.10	1/9/2027		
	140 (26)	—	\$56.85	1/8/2028		
	168 (27)	—	\$74.25	1/14/2029		
	201 (28)	—	\$49.20	1/13/2030		
	466 (29)	—	\$23.85	1/11/2031		
	1,466 (30)	—	\$13.76	1/10/2032		
	2,250 (31)	750 (31)	\$3.00	1/9/2033		
	2,000 (32)	2,000 (32)	\$3.08	1/9/2034		
	1,750 (33)	5,250 (33)	\$3.80	1/9/2035		
					1,374 (34)	\$2,556 (34)
					4,000 (35)	\$7,440 (35)
					11,250 (36)	\$20,925 (36)

** All option awards were made under and are governed by the terms of the Company's 2009 Plan, the 2015 Plan or the 2018 Plan.

*** Calculated by multiplying the closing market price of Lisata's common stock on December 31, 2025 by the number of shares of restricted stock held by the applicable Named Executive Officer.

- (1) Consists of options granted to Dr. Mazzo by the Compensation Committee on January 25, 2016.
- (2) Consists of options granted to Dr. Mazzo by the Compensation Committee on September 29, 2016.
- (3) Consists of options granted to Dr. Mazzo by the Compensation Committee on January 9, 2017.

- (4) Consists of options granted to Dr. Mazzo by the Compensation Committee on January 8, 2018.
- (5) Consists of options granted to Dr. Mazzo by the Compensation Committee on January 14, 2019.
- (6) Consists of options granted to Dr. Mazzo by the Compensation Committee on January 13, 2020, vesting in four equal annual installments beginning on the grant date.
- (7) Consists of options granted to Dr. Mazzo by the Compensation Committee on January 11, 2021, vesting in four equal annual installments beginning on the grant date.
- (8) Consists of options granted to Dr. Mazzo by the Compensation Committee on January 10, 2022, vesting in four equal annual installments beginning on the grant date.
- (9) Consists of options granted to Dr. Mazzo by the Compensation Committee on January 9, 2023, vesting in four equal annual installments beginning on the grant date.
- (10) Consists of options granted to Dr. Mazzo by the Compensation Committee on January 9, 2024, vesting in four equal annual installments beginning on the grant date.
- (11) Consists of options granted to Dr. Mazzo by the Compensation Committee on January 9, 2025, vesting in four equal annual installments beginning on the grant date.
- (12) Consists of restricted stock granted to Dr. Mazzo by the Compensation Committee on January 9, 2023, vesting in four equal annual installments beginning on the grant date.
- (13) Consists of restricted stock granted to Dr. Mazzo by the Compensation Committee on January 9, 2024, vesting in four equal annual installments beginning on the grant date.
- (14) Consists of restricted stock granted to Dr. Mazzo by the Compensation Committee on January 9, 2025, vesting in four equal annual installments beginning on the grant date.
- (15) Consists of options granted to Dr. Buck by the Compensation Committee on July 27, 2021, vesting in three equal annual installments beginning on the grant date.
- (16) Consists of options granted to Dr. Buck by the Compensation Committee on January 10, 2022, vesting in four equal annual installments beginning on the grant date.
- (17) Consists of options granted to Dr. Buck by the Compensation Committee on January 9, 2023, vesting in four equal annual installments beginning on the grant date.
- (18) Consists of options granted to Dr. Buck by the Compensation Committee on January 9, 2024, vesting in four equal annual installments beginning on the grant date.
- (19) Consists of options granted to Dr. Buck by the Compensation Committee on January 9, 2025, vesting in four equal annual installments beginning on the grant date.
- (20) Consists of restricted stock granted to Dr. Buck by the Compensation Committee on January 9, 2023, vesting in four equal annual installments beginning on the grant date.
- (21) Consists of restricted stock granted to Dr. Buck by the Compensation Committee on January 9, 2024, vesting in four equal annual installments beginning on the grant date.
- (22) Consists of restricted stock granted to Dr. Buck by the Compensation Committee on January 9, 2025, vesting in four equal annual installments beginning on the grant date.
- (23) Consists of options granted to Mr. Nisco by the Compensation Committee on January 25, 2016.
- (24) Consists of options granted to Mr. Nisco by the Compensation Committee on September 29, 2016.
- (25) Consists of options granted to Mr. Nisco by the Compensation Committee on January 9, 2017.
- (26) Consists of options granted to Mr. Nisco by the Compensation Committee on January 8, 2018.
- (27) Consists of options granted to Mr. Nisco by the Compensation Committee on January 14, 2019.
- (28) Consists of options granted to Mr. Nisco by the Compensation Committee on January 13, 2020, vesting in four equal annual installments beginning on the grant date.

- (29) Consists of options granted to Mr. Nisco by the Compensation Committee on January 11, 2021, vesting in four equal annual installments beginning on the grant date.
- (30) Consists of options granted to Mr. Nisco by the Compensation Committee on January 10, 2022, vesting in four equal annual installments beginning on the grant date.
- (31) Consists of options granted to Mr. Nisco by the Compensation Committee on January 9, 2023, vesting in four equal annual installments beginning on the grant date.
- (32) Consists of options granted to Mr. Nisco by the Compensation Committee on January 9, 2024, vesting in four equal annual installments beginning on the grant date.
- (33) Consists of options granted to Mr. Nisco by the Compensation Committee on January 9, 2025, vesting in four equal annual installments beginning on the grant date.
- (34) Consists of restricted stock granted to Mr. Nisco by the Compensation Committee on January 9, 2023, vesting in four equal annual installments beginning on the grant date.
- (35) Consists of restricted stock granted to Mr. Nisco by the Compensation Committee on January 9, 2024, vesting in four equal annual installments beginning on the grant date.
- (36) Consists of restricted stock granted to Mr. Nisco by the Compensation Committee on January 9, 2025, vesting in four equal annual installments beginning on the grant date.

Pension Benefits

We do not have any qualified or non-qualified defined benefit plans.

Non-qualified Deferred Compensation

We do not have any non-qualified defined contribution plans or other deferred compensation plans.

Ownership Requirements

Each of our officers subject to Section 16 of the Exchange Act (“Section 16 Officers”) are subject to stock ownership guidelines. On June 21, 2023, our Compensation Committee approved the Lisata Stock Ownership Policy (the “LSOP”), which instituted stock ownership guidelines in the interest of promoting and increasing equity ownership by our executives and to further align our executives’ long-term interests with those of our stockholders.

The following table outlines the stock ownership guidelines for our executives pursuant to the LSOP.

Position	Ownership Guidelines
President and Chief Executive Officer	3x base salary
All other Section 16 Officers	1x base salary

Officers subject to the LSOP are expected to comply by June 2028. As of April 28, 2026, all of our Section 16 Officers, including all of our named executive officers, are making appropriate progress toward the ownership guidelines.

LISATA DIRECTOR COMPENSATION

General Information

Directors who are employees of Lisata or its subsidiaries do not receive additional cash compensation for serving as directors. Lisata's non-employee directors are reimbursed for out-of-pocket travel expenses incurred in their capacity as Lisata directors. Pursuant to the 2018 Plan, all directors (including independent directors) are eligible to receive equity awards.

The following table sets forth information on all compensation to Lisata's directors (other than as reflected in the Summary Compensation Table) for the year ended December 31, 2025.

Name	Fees Earned		Total Compensation
	Or Paid in Cash	Stock Awards ⁽¹⁾	
Gregory B. Brown, M.D. ⁽²⁾	\$ 94,500	\$ 60,000	\$154,500
Steven M. Klosk, J.D. ⁽³⁾	\$ 60,000	\$ 60,000	\$120,000
Cynthia L. Flowers, M.B.A. ⁽⁴⁾	\$ 52,500	\$ 60,000	\$112,500
Heidi Henson ⁽⁵⁾	\$ 64,000	\$ 60,000	\$124,000
Mohammad Azab, M.D., M.B.A. ⁽⁶⁾	\$ 53,500	\$ 60,000	\$113,500
Total	<u>\$ 324,500</u>	<u>\$ 300,000</u>	<u>\$624,500</u>

- (1) Amounts shown under “Stock Awards” represent the aggregate grant date fair value computed in accordance with FASB ASC Topic 718, in accordance with SEC rules. See Note 9 to the Notes to the Consolidated Financial Statements in our 2025 Form 10-K for a discussion of assumptions made in such valuations. All stock awards, option awards and other shares discussed in this table were issued under Lisata's 2018 Plan, with a per share price generally equal to the fair market value of a share of our common stock on the date of grant.
- (2) On January 9, 2025, Dr. Brown was granted 15,789 restricted stock units, none of which had vested as of December 31, 2025.
- (3) On January 9, 2025, Mr. Klosk was granted 15,789 restricted stock units, none of which had vested as of December 31, 2025.
- (4) On January 9, 2025, Ms. Flowers was granted 15,789 restricted stock units, none of which had vested as of December 31, 2025.
- (5) On January 9, 2025, Ms. Henson was granted 15,789 restricted stock units, none of which had vested as of December 31, 2025.
- (6) On January 9, 2025, Dr. Azab was granted 15,789 restricted stock units, none of which had vested as of December 31, 2025.

The Company's Board of Directors' Compensation Plan (the “Directors' Compensation Plan”), which is only applicable to our non-employee directors, provided the following in fiscal year 2025:

- an annual cash retainer for each non-employee director of \$40,000;
- an additional annual cash compensation retainer of \$35,000 for the non-executive chair;
- an annual cash retainer for serving as chairperson of a committee as follows: Audit (\$18,000); Compensation (\$12,000); Nominating and Governance (\$9,000); Science and Technology (\$9,000);
- an annual cash retainer for serving as a member of a committee as follows: Audit (\$8,000); Compensation (\$6,000); Nominating and Governance (\$4,500); and Science and Technology (\$4,500);
- new non-employee directors receive an initial grant of restricted stock units with a value of 2x the annual grant with the number of shares to be issued on the grant date calculated based on the grant date fair value with one-third vesting annually on each of the first, second and third anniversaries of the grant date; and

- an annual equity grant on January 9, 2025, a grant of restricted stock units with a value of \$60,000, vesting at one year from the grant date.

The effective date for the annual equity grant to non-employee directors in fiscal year 2025 was January 9, 2025.

INCENTIVE COMPENSATION RECOUPMENT POLICY

On December 5, 2017, the Company adopted an Incentive Compensation Recoupment Policy that applies to an employee of the Company who is serving as an “officer” within the meaning of Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended.

The Compensation Committee of the Board may seek Recoupment of any Recoverable Payment, when in its judgment, after reviewing relevant facts and circumstances, it determines that: (a) an Executive (i) engaged in serious misconduct, or (ii) failed to supervise a subordinate employee who engaged in serious misconduct which the Executive knew, or was reckless in not knowing, was occurring, and (b) such misconduct resulted in a material violation of law or a written Company policy that caused significant financial or reputational harm to the Company. As used in this Policy, “serious misconduct” may be only found to have occurred where an Executive or a supervised employee acted knowingly, intentionally, or recklessly in violating a law or written Company policy. For the avoidance of doubt, an Executive’s business judgment made in good faith and in the reasonable belief that such judgments and related actions were in or not opposed to the best interests of the Company shall not subject the Executive’s Incentive Compensation to Recoupment.

"Incentive Compensation" means (i) any equity or equity-based award granted on or after the Effective Date, and (ii) any cash-based performance or incentive award (i.e., bonus or cash incentive plan payment, including any amounts deferred with respect thereto) made to an Executive with respect to the Company’s 2019 fiscal year or any subsequent fiscal year.

The determination by the Committee whether and the extent to which to seek Recoupment may be influenced by a variety of factors, including, but not limited to, (i) the elements of the compensation received by the Executive, (ii) retention, promotion, or succession planning considerations, (iii) pay equity factors, (iv) whether the underlying conduct was an isolated occurrence, (v) feasibility and cost of implementation, (vi) legal and compliance factors, (vii) whether other disciplinary actions have been taken against the Executive, and (viii) the objective of administering the Policy in a way that does not discourage settlement of disputes when settlements are in the best long-term interests of the Company and its stockholders.

Based on the facts and circumstances, the Committee may decide on the appropriate Recoupment method, including whether to seek Recoupment of Recoverable Payments already paid or otherwise seek Recoupment (totally or partially) of Recoverable Payments that have not vested or have not been paid. However, the Committee may not seek Recoupment of any Recoverable Payments (a) following a change in control (as defined in the Executive’s employment agreement) or (b) that were awarded more than three years prior to the first event giving rise to the Recoupment. This Policy shall operate prospectively from the Effective Date and shall be construed so as not to violate any legally binding commitment of the Company arising prior to the Effective Date. Recoupment determinations pursuant to this Policy shall only be made to the extent permitted by law, and this Policy shall be interpreted so as not to violate any law or regulation.

ITEM 12. SECURITY OWNERSHIP OF MANAGEMENT AND CERTAIN BENEFICIAL OWNERS

The tables below provide information regarding the beneficial ownership of Lisata's common stock as of April 28, 2026 by: (i) each of Lisata's directors; (ii) Lisata's Named Executive Officers; (iii) all of Lisata's current directors and executive officers as a group; and (iv) each beneficial owner of more than five percent of Lisata's common stock.

Beneficial ownership is determined in accordance with SEC rules and regulations, and generally includes voting power or investment power with respect to securities held. Unless otherwise indicated and subject to applicable community property laws, we believe that each of the Lisata stockholders named in the table below has sole voting and investment power with respect to the shares shown as beneficially owned. Securities that may be beneficially acquired within 60 days after April 28, 2026 are deemed to be beneficially owned by the person holding such securities for the purpose of computing the ownership of such person, but are not treated as outstanding for the purpose of computing the ownership of any other person.

The tables below list the number and percentage of shares beneficially owned based on 9,106,391 shares of Lisata's common stock outstanding as of April 28, 2026. Unless otherwise indicated below, the address for each beneficial owner listed is c/o Lisata Therapeutics, Inc., P.O. Box 173, Liberty Corner, New Jersey 07938.

Directors and Named Executive Officers

Name of Beneficial Owner	Total Shares of Common Stock Beneficially Owned (#)	Percentage
5%+ Stockholders:		
Erkki Ruoslahti, M.D., Ph.D	1,267,798 (1)	13.7%
Directors and Named Executive Officers:		
David J. Mazzo, Ph.D., President and Chief Executive Officer	443,876 (2)	4.8%
Kristen K. Buck, M.D., Executive Vice President of Research & Development and Chief Medical Officer	200,739 (3)	2.2%
James Nisco, Senior Vice President, Finance and Treasury and Chief Accounting Officer	46,439 (4)	*
Tariq Imam, Senior Vice President, Business Development and Operations and General Counsel	49,018 (5)	*
Gregory B. Brown, M.D., Chairman of the Board	65,662 (6)	*
Cynthia L. Flowers, M.B.A., Director	64,990 (7)	*
Steven M. Klosk, J.D., Director	65,625 (8)	*
Heidi Henson, Director	87,297 (9)	*
Mohammad Azab, M.D., M.B.A., Director	74,469 (10)	*
All directors and executive officers as a group (nine individuals)	1,098,115 (11)	11.3%

* Beneficial ownership is less than 1%

- (1) Includes options to purchase up to 164,798 shares of our common stock which are exercisable within 60 days of April 28, 2026. Dr. Ruoslahti's address is 3132 Don Rolando, Escondido CA 92025.
- (2) Includes options to purchase up to 131,976 shares of our common stock which are exercisable within 60 days of April 28, 2026.
- (3) Includes options to purchase up to 107,277 shares of our common stock which are exercisable within 60 days of April 28, 2026.
- (4) Includes options to purchase up to 14,128 shares of our common stock which are exercisable within 60 days of April 28, 2026.
- (5) Includes options to purchase up to 12,940 shares of our common stock which are exercisable within 60 days of April 28, 2026.

- (6) Includes 64,927 fully vested restricted stock units that may be settled by issuing shares of common stock within 60 days of April 28, 2026 and options to purchase up to 459 shares of our common stock which are exercisable within 60 days of April 28, 2026.
- (7) Includes 64,990 fully vested restricted stock units that may be settled by issuing shares of common stock within 60 days of April 28, 2026.
- (8) Includes 64,927 fully vested restricted stock units that may be settled by issuing shares of common stock within 60 days of April 28, 2026 and options to purchase up to 266 shares of our common stock which are exercisable within 60 days of April 28, 2026.
- (9) Includes 55,269 fully vested restricted stock units that may be settled by issuing shares of common stock within 60 days of April 28, 2026 and options to purchase up to 32,028 shares of our common stock which are exercisable within 60 days of April 28, 2026.
- (10) Includes 74,469 fully vested restricted stock units that may be settled by issuing shares of common stock within 60 days of April 28, 2026.
- (11) Includes 324,582 fully vested restricted stock units that may be settled by issuing shares of common stock within 60 days of April 28, 2026 and options to purchase up to 299,074 shares of our common stock which are exercisable within 60 days of April 28, 2026.

Equity Compensation Plan Information

The following table provides information as of December 31, 2025 regarding shares of our common stock that may be issued under our existing equity compensation plans, including our 2018 Equity Incentive Compensation Plan (the “2018 Plan”), our 2015 Equity Compensation Plan (the “2015 Plan”), our 2009 Stock Option and Incentive Plan (the “2009 Plan”), and our amended 2017 Employee Stock Purchase Plan (the “Amended 2017 ESPP”).

Equity Compensation Plan Information			
	Number of securities to be issued upon exercise of outstanding options (1)	Weighted Average exercise price of outstanding options and rights	Number of securities remaining available for future issuance under equity compensation plan (excluding securities referenced in column (a))
Equity compensation plans approved by security holders (2)	1,502,881	\$6.17	478,010 (3)
Equity compensation plans not approved by security holders	0	—	0
(1)	Includes stock options only; does not include purchase rights accruing under the Amended 2017 ESPP Plan because the purchase price (and therefore the number of shares to be purchased) will not be determined until the end of the purchase period.		
(2)	Consists of the 2018 Plan, the 2015 Plan, the 2009 Plan, and the Amended 2017 ESPP.		
(3)	Includes shares available for future issuance under the 2018 Plan and the Amended 2017 ESPP.		

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Related Party Transaction Policies

The Audit Committee of the Lisata Board is responsible for reviewing and approving or ratifying all related party transactions. Our Board, acting upon the recommendation of its Audit Committee, has adopted a written policy with regard to related party transactions. The policy provides that related party transactions shall be brought to management's and the Board's attention. The procedures specify that at meetings of the Audit Committee, the Audit Committee will be provided with the details of each new, existing or proposed related party transaction, including the terms of the transaction, the business purpose, and the respective benefits to the Company and the relevant related party. The policy sets forth certain factors that the Audit Committee is to take into consideration in determining whether to approve a related party transaction, which include:

- whether the terms of the transaction are fair to the Company and on the same basis as would apply if the transaction did not involve a related party;
- the business reasons for the Company to enter into the transaction;
- whether the transaction would impair the independence of an independent director; and
- whether the transaction would present an improper conflict of interest for any director or executive officer, taking into account the size of the transaction, the overall financial position of the director, executive officer or other related party, the direct or indirect nature of the director's, executive officer's or other related party's interest in the transaction and the ongoing nature of any proposed relationship, and any other factors the Audit Committee deems relevant.

The procedures provide that in the event a member of the Audit Committee has an interest in the transaction under discussion, he will abstain from voting on the approval of the transaction, but may, if so requested by the chair of the Audit Committee and permitted under Nasdaq regulations, participate to the extent requested in discussions of the transaction. By "related party transaction," we mean a transaction requiring disclosure under Item 404(a) of Regulation S-K between the Company or any of its subsidiaries, on the one hand, and an executive officer, director, person known to be a 5% beneficial owner of the Company, or an immediate family member of any of the foregoing, on the other hand.

During the fiscal year ended December 31, 2025, we did not engage in any related party transactions.

Director Independence

The current Lisata Board members consist of Dr. Brown, Dr. Azab, Ms. Flowers, Ms. Henson, Mr. Klosk and Dr. Mazzo. The Lisata Board has reviewed the materiality of any relationship that each of our directors has with Lisata, either directly or indirectly. Based upon this review, the Lisata Board has determined that Dr. Brown, Dr. Azab, Ms. Flowers, Ms. Henson and Mr. Klosk are each "independent directors" applying the definition of independence under the listing standards of Nasdaq.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Grant Thornton LLP (New York, NY; PCAOB ID Number 248) was engaged to serve as Lisata's' independent registered public accounting firm in 2025 and 2024 and accordingly, audited Lisata's financial statements for the fiscal years ended December 31, 2025 and 2024. The following table sets forth a summary of the fees billed or expected to be billed to us by Grant Thornton LLP for professional services rendered for the fiscal years ended December 31, 2025 and 2024.

Fee Category	Fiscal 2025 Fees	Fiscal 2024 Fees
Audit Fees ⁽¹⁾	\$ 422,180	\$ 483,000
Audit-Related Fees ⁽²⁾	\$ —	\$ —
Tax Fees ⁽³⁾	\$ —	\$ —
All Other Fees ⁽⁴⁾	\$ —	\$ —
Total Fees	<u>\$ 422,180</u>	<u>\$ 483,000</u>

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- (1) Audit Fees consist of aggregate fees billed or expected to be billed for professional services rendered for the audit of Lisata's annual consolidated financial statements included in Lisata's Annual Reports on Form 10-K and review of the interim consolidated financial statements included in Quarterly Reports on Form 10-Q or services that are normally provided by the independent registered public accounting firm in connection with statutory and regulatory filings or engagements for the fiscal years ended December 31, 2025 and 2024, respectively.
- (2) Audit-Related Fees consist of aggregate fees billed for assurance and related services that are reasonably related to the performance of the audit or review of Lisata's consolidated financial statements and are not reported under "Audit Fees."
- (3) Tax Fees consist of aggregate fees billed or expected to be billed for professional services rendered for tax compliance, tax advice and tax planning. These fees related to preparation of Lisata's federal and state income tax returns and other tax compliance activities.
- (4) All Other Fees consist of aggregate fees billed for products and services provided by Grant Thornton (as applicable), other than those disclosed above.

The Audit Committee is responsible for the appointment, compensation and oversight of the work of the independent registered public accounting firm and approves in advance any services to be performed by the independent registered public accounting firm, whether audit-related or not. The Audit Committee reviews each proposed engagement to determine whether the provision of services is compatible with maintaining the independence of the independent registered public accounting firm. All of the fees shown above were pre-approved by the Audit Committee.

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

The following documents are being filed as part of this Report:

(a)(3) EXHIBITS:

The following is a list of exhibits filed (or furnished, where specified) as part of this Annual Report on Form 10-K/A. Exhibits that were previously filed are described below and are incorporated by reference. For exhibits incorporated by reference, the location of the exhibit in the previous filing is indicated.

Exhibit	Description
2.1 *	Agreement and Plan of Merger, dated March 6, 2026, by and among the Company, Kuva Labs, Inc. and Kuva Acquisition Corp. (filed as Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the SEC on March 9, 2026).
3.1	Certificate of Amendment (Reverse Stock Split) to the Amended and Restated Certificate of Incorporation, dated September 14, 2022 (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on September 15, 2022).
3.2	Certificate of Amendment (Name Change) to the Amended and Restated Certificate of Incorporation, dated September 15, 2022 (filed as Exhibit 3.2 to the Company's Current Report on Form 8-K, filed with the SEC on September 15, 2022).
3.3	Amended and Restated Certificate of Incorporation of Lisata Therapeutics, Inc., as amended, effective July 27, 2016 (filed as Exhibit 3.1 to the Company's on Form 10-Q for the quarter ended June 30, 2016, filed with the SEC on August 9, 2016).
3.4	Amended and Restated By-Laws of the Lisata Therapeutics, Inc. as amended, effective as of July 27, 2016 (filed as Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, filed with the SEC on August 9, 2016).
3.5	Amendments to Amended and Restated Bylaws of Lisata Therapeutics, Inc., effective as of September 18, 2017 (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on September 21, 2017).
4.1	Description of Capital Stock (filed as Exhibit 4.3 to the Company's Annual Report on Form 10-K, for the year ended December 31, 2019, filed with the SEC on March 5, 2020).
4.2	Form of Warrant (filed as Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on April 24, 2020).
4.3	Form of Warrant (filed as Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on May 26, 2020).
4.4	Form of Warrant (filed as Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on July 10, 2020).
4.5	Form of Warrant (filed as Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on January 25, 2021).
10.1 +	Director Compensation Policy, dated April 21, 2021 (filed as Exhibit 10.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 30, 2023).
10.2 +	2018 Equity Incentive Compensation Plan, effective June 20, 2018, as amended on June 18, 2020, June 16, 2021, September 15, 2022, June 14, 2023 and June 27, 2024 (filed as Exhibit 10.2 to the Company's Annual Report on Form 10-K, for the year ended December 31, 2025, filed with the SEC on March 12, 2026).

- 10.3 + 2015 Equity Incentive Compensation Plan, effective July 15, 2015 (filed as Exhibit 10.4 to the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 30, 2023).
- 10.4 + Amended & Restated 2009 Equity Compensation Plan, effective October 4, 2012 (filed as Exhibit 10.5 to the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 30, 2023).
- 10.5 + 2017 Employee Stock Purchase Plan, effective as of March 28, 2017, as amended on June 20, 2018, June 14, 2023 and June 27, 2024 (filed as Exhibit 10.5 to the Company's Annual Report on Form 10-K, for the year ended December 31, 2025, filed with the SEC on March 12, 2026).
- 10.6 + Form of Indemnification Agreement between the Company and each of its directors and officers (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on September 15, 2022).
- 10.7 + Amended and Restated Employment Agreement with David J. Mazzo, dated March 19, 2021 (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on March 19, 2021).
- 10.8 + Second Amended and Restated Employment Agreement, by and between the Company and David J. Mazzo, Ph.D., dated as of June 10, 2025 (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on June 13, 2025)
- 10.9 + Amended and Restated Employment Agreement, by and between the Company and Kristen K. Buck, M.D., dated as of June 10, 2025 (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on June 13, 2025).
- 10.10 + Amended and Restated Separation Benefits Agreement, by and between the Company and James Nisco, dated as of June 10, 2025 (filed as Exhibit 10.3 to the Company's Current Report on Form 8-K, filed with the SEC on June 13, 2025).
- 10.11 + Amended and Restated Separation Benefits Agreement, by and between the Company and Tariq Imam, dated as of June 10, 2025 (filed as Exhibit 10.4 to the Company's Current Report on Form 8-K, filed with the SEC on June 13, 2025).
- 10.12 + Cend 2016 Equity Incentive Plan, including all amendments thereto (filed as Exhibit 99.1 to the Company's Registration Statement on Form S-8, filed with the SEC on October 17, 2022).
- 10.13 At The Market Offering Agreement, dated June 4, 2021, by and between Caladrius Biosciences, Inc. and H.C. Wainwright & Co., LLC (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on June 4, 2021).
- 10.14 Exclusive License Agreement, dated December 1, 2015, by and between Cend Therapeutics, Inc. (f/k/a DrugCendR, LLC) and Sanford Burnham Prebys Medical Discovery Institute (filed as Exhibit 10.18 to the Company's Registration Statement on Form S-4, filed with the SEC on June 15, 2022).
- 10.15 First Amendment to Exclusive License Agreement, dated March 8, 2016, by and between Cend Therapeutics, Inc. (f/k/a DrugCendR, LLC) and Sanford Burnham Prebys Medical Discovery Institute (filed as Exhibit 10.19 to the Company's Registration Statement on Form S-4, filed with the SEC on June 15, 2022).
- 10.16 Second Amendment to Exclusive License Agreement, dated May 10, 2019, by and between Cend Therapeutics, Inc. (f/k/a DrugCendR, LLC) and Sanford Burnham Prebys Medical Discovery Institute (filed as Exhibit 10.20 to the Company's Registration Statement on Form S-4, filed with the SEC on June 15, 2022).
- 10.17 Third Amendment to Exclusive License Agreement, dated September 24, 2020, by and between Cend Therapeutics, Inc. (f/k/a DrugCendR, LLC) and Sanford Burnham Prebys Medical Discovery Institute (filed as Exhibit 10.21 to the Company's Registration Statement on Form S-4, filed with the SEC on June 15, 2022).

10.18	Exclusive License and Collaboration Agreement, dated as of November 30, 2024, by and between Lisata Therapeutics, Inc. and Kuva Labs, Inc. (filed as Exhibit 10.18 to the Company's Annual Report on Form 10-K, for the year ended December 31, 2025, filed with the SEC on March 12, 2026).
10.19	Non-Exclusive License Agreement, dated as of October 8, 2025, by and between Lisata Therapeutics, Inc. and Catalent, Inc. (filed as Exhibit 10.19 to the Company's Annual Report on Form 10-K, for the year ended December 31, 2025, filed with the SEC on March 12, 2026).
14.1	Code of Ethics for Senior Financial Officers, effective as of November 7, 2022 (filed as Exhibit 14.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 30, 2023).
19.1	Insider Trading Policy, effective as of October 30, 2015 (filed as Exhibit 19.1 on the Company's Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 29, 2024).
97	Incentive Recoupment Policy, effective as of March 28, 2023 (filed as Exhibit 97 to the Company's Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 29, 2024).
21.1	Subsidiaries of Lisata Therapeutics, Inc. (filed as Exhibit 21.1 to the Company's Annual Report on Form 10-K, for the year ended December 31, 2025, filed with the SEC on March 12, 2026).
23.1	Consent of Grant Thornton LLP. (filed as Exhibit 23.1 to the Company's Annual Report on Form 10-K, for the year ended December 31, 2025, filed with the SEC on March 12, 2026).
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 pursuant to 18 U.S.C. Section 1350, as adopted pursuant Section 906 of the Sarbanes-Oxley Act of 2002 (filed as Exhibit 32.1 to the Company's Annual Report on Form 10-K, for the year ended December 31, 2025, filed with the SEC on March 12, 2026).
32.2 †	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant Section 906 of the Sarbanes-Oxley Act of 2002 (filed as Exhibit 32.2 to the Company's Annual Report on Form 10-K, for the year ended December 31, 2025, filed with the SEC on March 12, 2026).
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

+ Management contract or compensatory plan, contract or arrangement required to be filed as an exhibit to this Form 10-K pursuant to Item 15(b) of Form 10-K.

† Furnished herewith.

* Schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company agrees to furnish supplementally a copy of any such schedule or exhibit to the SEC upon request.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in Basking Ridge (Bernards Township), State of New Jersey, on April 28, 2026.

LISATA THERAPEUTICS, INC.

By: /s/ David J. Mazzo, PhD

Name: David J. Mazzo

Title: President & Chief Executive Officer
(Principal Executive Officer)

Pursuant to the requirements of the Securities 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
<u>/s/ David J. Mazzo</u> David J. Mazzo, PhD	Director and President and Chief Executive Officer (Principal Executive Officer)	April 28, 2026
<u>/s/ James Nisco</u> James Nisco	SVP, Finance and Treasury and Chief Accounting Officer (Principal Financial Officer and Principal Accounting Officer)	April 28, 2026
<u>/s/ Gregory B. Brown</u> Gregory B. Brown, MD	Chairman of the Board of Directors	April 28, 2026
<u>/s/ Mohammad Azab</u> Mohamad Azab, MD, MBA	Director	April 28, 2026
<u>/s/ Cynthia L. Flowers</u> Cynthia L. Flowers, MBA	Director	April 28, 2026
<u>/s/ Heidi Henson</u> Heidi Henson	Director	April 28, 2026
<u>/s/ Steven M. Klosk</u> Steven M. Klosk, JD	Director	April 28, 2026

