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, 2023

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	22-2343568
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
110 Allen Road, 2nd Floor, Basking Ridge, New Jersey	07920
(Address of principal executive offices)	(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, 2023 (the last business day of the Registrant's most recently completed second fiscal quarter) was approximately $25.1 million, computed by reference to the last sale price of $3.70 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 February 29, 2023**
Common stock, $0.001 par value per share	8,307,433 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 2024 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, 2023.

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.

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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" 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:

- 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;
- 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, "we," "us," "our," "Lisata" and 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 major diseases. Our lead investigational product candidate, LSTA1, is designed to activate a novel uptake pathway that allows co-administered or tethered (i.e., molecularly bound) anti-cancer drugs to target and penetrate solid tumors more effectively. LSTA1 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 unlikely to be affected. LSTA1 also has the potential to modify the tumor microenvironment ("TME"), thereby making tumors more susceptible to immunotherapies and inhibiting the metastasis cascade (i.e., the spread of cancer to other parts of the body). We and our collaborators have amassed significant non-clinical data demonstrating enhanced delivery of a range of existing and emerging anti-cancer therapies, including chemotherapeutics, immunotherapies and RNA-based therapeutics. To date, LSTA1 has also demonstrated favorable safety, tolerability and activity in completed and ongoing clinical trials designed to enhance delivery of standard-of-care chemotherapy for pancreatic cancer. Currently, LSTA1, is the subject of Phase 2a and 2b clinical studies being conducted globally in a variety of solid tumor types, including metastatic pancreatic ductal adenocarcinoma (mPDAC), cholangiocarcinoma, head and neck cancer, appendiceal cancer, colon cancer and glioblastoma multiforme in combination with a variety of anti-cancer regimens.

Our legacy CD34+ cell therapy technology was the subject of several clinical trials targeting an array of diseases, among them, critical limb ischemia, coronary microvascular dysfunction, and diabetic kidney disease. Further development of such programs would require significantly larger studies and capital investment and thus, development by Lisata would only be continued if a strategic partner that can contribute the necessary capital for future development is identified.

Our leadership team has 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 traded names included herein are the property of their respective owners.

Merger with Cend Therapeutics, Inc. and Name Change

On September 15, 2022, we, then operating as Caladrius Biosciences, Inc. ("Caladrius"), completed our acquisition (the "Merger") of Cend Therapeutics, Inc. ("Cend"), in accordance with the terms of the Agreement and Plan of Merger and Reorganization (the "Merger Agreement"), dated as of April 26, 2022, by and among us, Cend and CS Cedar Merger Sub, Inc. ("Merger Sub").

Pursuant to the terms set forth in the Merger Agreement and effective September 15, 2022 (the "Effective Time"): (i) Merger Sub merged with and into Cend, with Cend surviving as our wholly owned subsidiary, (ii) we changed our name to Lisata Therapeutics, Inc., and (iii) we effected a 1:15 reverse stock split of our common stock (the "Reverse Stock Split") prior to the Effective Time. At the Effective Time, each share of Cend's common stock outstanding immediately prior to the Effective Time was converted into the right to receive shares of our common stock, based on an exchange ratio of 0.5338, after taking into account the Reverse Stock Split (the "Exchange Ratio"). In connection with the Merger close, we issued an aggregate of 3,772,768 shares of common stock, based on the Exchange Ratio, to holders of Cend, in exchange for all of the Cend capital stock outstanding immediately prior to the closing of the Merger.

Pursuant to the Merger Agreement, we assumed all of the outstanding and unexercised options to purchase shares of Cend capital stock under the 2016 Equity Incentive Plan, and, in connection with the Merger, such options were converted into options to purchase shares of our common stock based on the Exchange Ratio. At the closing of the Merger, we assumed Cend's stock options to purchase an aggregate of 1,227,776 shares of our common stock.

Caladrius was considered to be the accounting acquirer based on the terms of the Merger Agreement and certain factors including: (i) Caladrius owned approximately 52% of our outstanding shares of common stock immediately following the close of the Merger; (ii) although both entities contributed to our new management team, the Caladrius team had more individuals on the management team and holds the chief executive officer ("CEO"), chief medical officer ("CMO") and other senior management roles; (iii) Caladrius paid a premium to acquire Cend's assets; and (iv) Caladrius was significantly larger than Cend regarding total assets, operations, and research and development activities. The Merger was accounted for as an asset acquisition as substantially all of the fair value is concentrated in in-process research and development ("IPR&D"). Cend's assets (except for cash and working capital) were measured and recognized as an allocation of the transaction price based on their relative fair values as of the transaction date with any value associated with IPR&D with no alternative future use being expensed as reported in the consolidated statement of operations. The prior reported operating results prior to the closing of the Merger are those of Caladrius alone.

Reverse Stock Split

On September 14, 2022, in connection with the Merger, we implemented the Reverse Stock Split, which was approved at our annual meeting of stockholders on September 13, 2022. The Reverse Stock Split became effective on September 14, 2022 at 5:00 pm, and our common stock began trading on The Nasdaq Capital Market on a post-split basis at the open of business on September 15, 2022. As of September 14, 2022, every fifteen shares of our issued and outstanding common stock (and such shares held in treasury) were automatically converted into one share of common stock, without any change in the par value per share. In addition, proportionate adjustments were made to the per share exercise price and the number of shares issuable upon the exercise of all outstanding stock options, stock appreciation rights, convertible notes and warrants to purchase shares of common stock, the number of shares issuable upon the vesting of all restricted stock awards, and the number of shares of common stock reserved for issuance pursuant to our equity incentive compensation plans. Any stockholder who would otherwise be entitled to a fractional share of common stock created as a result of the Reverse Stock Split received a cash payment equal to the product of such resulting fractional interest in one share of common stock multiplied by the closing trading price of the common stock on September 15, 2022. The Reverse Stock Split was effectuated in order to increase the per share trading price of our common stock to satisfy the $1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market.

All share and per share amounts of common stock, options and warrants in the accompanying financial statements have been restated for all periods presented to give retroactive effect to the Reverse Stock Split. Accordingly, the consolidated statements of equity reflect the impact of the Reverse Stock Split by reclassifying from "common stock" to "additional paid-in capital" in an amount equal to the par value of the decreased shares resulting from the Reverse Stock Split.

Development Programs

Targeted Solid Tumor Penetration via CendR Active Transport

Many solid tumor cancers, including pancreatic ductal adenocarcinoma ("PDAC"), and cholangiocarcinoma, are surrounded by dense fibrotic tissue, or stroma. This limits the efficacy of current chemotherapies for these cancers. Emerging immunotherapy treatments, including checkpoint inhibitors, adoptive cell therapies such as chimeric antigen receptor T cells, as well as nucleic acid-based therapies, such as short interfering RNA ("siRNA"), antisense oligonucleotides, and messenger RNAs ("mRNAs") also face challenges in penetrating solid tumors. Many tumors also exhibit an immunosuppressive TME, which suppresses patients' immune systems' ability to fight their cancer and can limit effectiveness of immunotherapies and/or contribute to metastases. These factors negatively impact the ability of many therapeutic agents to effectively treat these cancers.

To address the tumor stroma's role as a primary impediment to effective treatment, our approach is to activate the C-end rule ("CendR"), or CendR system, a naturally occurring active transport system. Our lead investigational drug, LSTA1 (a specific internalizing R-G-D or iRGD peptide), activates this transport system in a tumor-specific manner (Sugahara, Science, 2010). LSTA1 enables more selective and efficient uptake of systemically administered anti-cancer drugs resulting in more intratumoral drug accumulation. The overall result is enhanced anticancer activity without an increase in adverse side effects. While it is possible to couple/tether or conjugate some anticancer drugs to LSTA1, we believe that the co-administration approach is an advantage because it does not create a new chemical entity with its attendant development and regulatory hurdles, thereby providing an anticipated faster-to-clinic and faster-to-market product opportunity for a range of co-administration therapies.

LSTA1 has demonstrated favorable safety, tolerability, and activity to date in clinical trials to enhance delivery of standard-of-care chemotherapy for mPDAC. LSTA1's cancer-targeted delivery may enable such emerging treatment modalities to treat a range of solid tumors potentially more effectively.

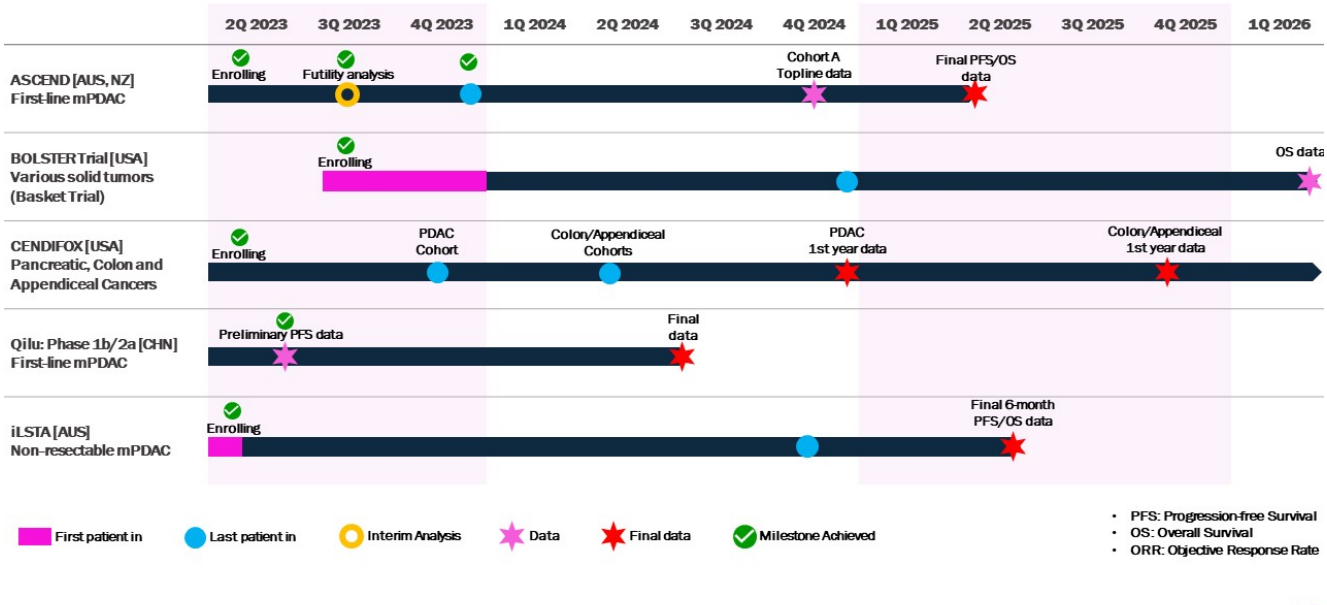
LSTA1 as a treatment for solid tumor cancers in combination with other anti-cancer agents

LSTA1 is an investigational drug that actuates the CendR active transport mechanism. LSTA1 has the potential to modify the TME, making it less immunosuppressive and thereby making the tumor more susceptible to attack by the immune system and inhibiting the metastasis cascade. It targets tumor vasculature, endothelial cells, tumor cells and some intratumoral immunosuppressive cells by its affinity for alpha-v, beta-3 and beta-5 integrins that are upregulated on these cells. LSTA1 is a nine amino acid cyclic internalizing RGD ("iRGD") peptide that, once bound to these integrins, is cleaved by proteases expressed in tumors to release a peptide fragment, called a CendR peptide fragment. The CendR peptide fragment then binds to an adjacent receptor, called neuropilin-1, also upregulated in solid tumors, to activate a novel uptake pathway that allows circulating moieties such as anticancer drugs to more selectively and effectively penetrate solid tumors. The ability of LSTA1 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 with the results from Lisata, collaborators and research groups around the world having been the subject of over 300 related scientific publications.

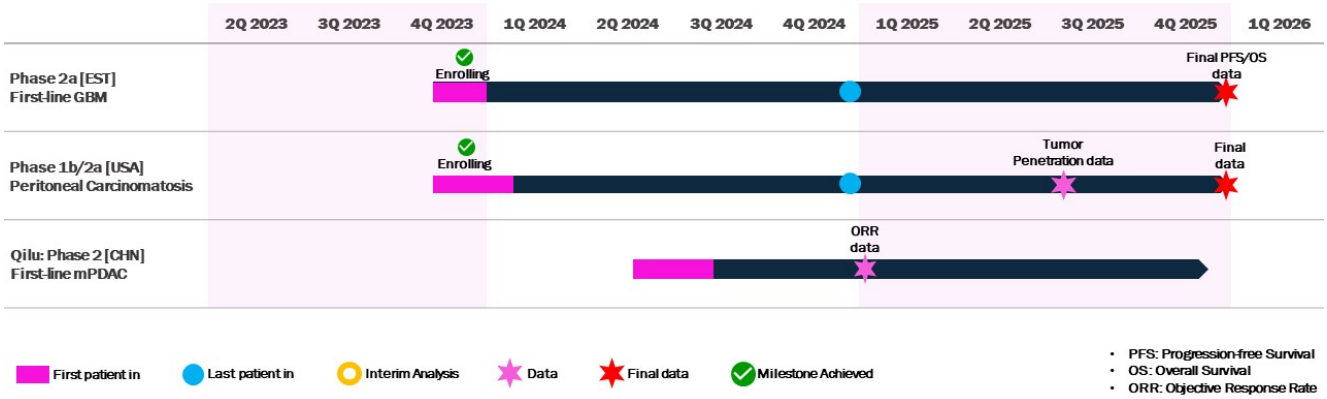
With regard to clinical development, LSTA1 is the subject of a completed Phase 1b clinical trial of 31 first-line mPDAC patients, of which 29 were evaluable. Results from the trial showed that the safety profile of the LSTA1 combination regimen was similar to standard of care ("SoC") alone with LSTA1 being well-tolerated with no-dose limiting toxicities. An Objective Response Rate ("ORR") of 59% was observed, compared to the 23% ORR observed in the "MPACT" clinical trial that served as the basis for approval of nab-paclitaxel for use in combination with gemcitabine for the treatment of first line, mPDAC (Von Hoff, et al. 2013). A Disease Control Rate ("DCR") (partial and complete responses plus stable disease) of over 79% was also observed in comparison to a DCR of 48% observed in the MPACT trial. Reduction in the level of circulating tumor biomarker CA19-9 was observed in 96% of patients versus 61% in the MPACT trial. Importantly, median progression-free survival and median overall survival of nearly ten months and over thirteen months were observed versus less than six months and less than nine months, respectively, in the MPACT trial. These results have been published in The Lancet Gastroenterology and Hepatology (Dean, et al. 2022).

Additionally, LSTA1 is the subject of multiple ongoing and planned clinical trials being conducted globally in a variety of solid tumor types and in combination with several chemotherapy and immunotherapy anti-cancer regimens. The following diagram summarizes these studies.

Anticipated key milestones



Anticipated key milestones (contd.)



TECHNOLOGY COLLABORATION AND OUT-LICENSING OPPORTUNITIES

Pancreatic Cancer & Advanced Solid Tumors (LSTA1: CendR Platform®)

Our lead investigational drug candidate from the CendR Platform®, LSTA1, holds broader potential to be combined as a co-administration treatment with an array of anti-cancer 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 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 LSTA1 and CendR Platform® patent portfolio comprises the following:

a. Three pending patent applications in the United States;

b. Fourteen pending patent applications outside the United States; and

c. Pending claims covering, inter alia, methods for reducing the volume of a tumor using LSTA1 in combination with at least one anti-cancer agent or therapy; methods of treating pancreatic cancer using LSTA1 in combination with gemcitabine and/or nab-paclitaxel and treating tumors with iRGD and a cytokine.

Product Opportunity for Pancreatic ductal adenocarcinoma (PDAC)

In the United States, there are approximately 64,000 new cases of pancreatic cancer diagnosed annually. Outside of the United States, there are an additional 434,000 annual pancreatic cancer diagnoses. PDAC accounts for more than 80% of all pancreatic cancer cases, so worldwide, nearly 397,000 annual incidences of PDAC are diagnosed. Further, PDAC is one of the most aggressive and lethal malignancies, with a 5-year survival rate of 11%, resulting in approximately 50,000 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 health care 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- 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. 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 1*: 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. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug as a requirement for marketing authorization.

- *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 also recently amended the FD&C Act 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. It is unknown at this time how the diversity action plan may affect Phase 3 trial planning and timing or what specific information FDA will expect in such plans, but 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 and efficacy 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.

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, 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. 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 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 health care 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 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.

Finally, 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.

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, Fast Track designation, breakthrough therapy designation and priority review do not change 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. Under these recent amendments to the FD&C Act, the agency may require 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 recently 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. Waiver of pediatric data requirements also does not apply to anti-cancer therapies in cases where the molecular target is found in pediatric tumors.

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, bipartisan legislation introduced in 2023 in the House of Representatives would increase funding for pediatric trials; mandate that drugs for rare diseases be studied in children; and grant 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 a 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 2024 that additional user fee is over $1.3 million.

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

In 2020, the Rare Pediatric Disease Priority Review Voucher Program was extended by Congress. Under the current statutory sunset provisions, after September 30, 2024, FDA may only award a voucher for an approved rare pediatric disease product application if the sponsor has RPDD for the drug, and that designation was granted by September 30, 2024. After September 30, 2026, FDA may not award any rare pediatric disease PRVs unless the program is extended. Congress will need to take action to further extend FDA's authority to administer this program, either in the context of the five-year FDA user fee reauthorization cycle (which is expected to take place in 2027) or sooner through another legislative vehicle, otherwise it will terminate entirely after September 2026.

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 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 health care 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 mandated phased-in and resource-intensive traceability and verification obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10-year period that culminated in November 2023. FDA has announced a one-year stabilization period to November 2024, giving entities subject to the DSCSA additional time to finalize interoperable tracking systems and to ensure supply chain continuity. 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 Health Care 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 health care 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 health care 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 health care 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 health care 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 health care laws, are punishable by criminal and civil sanctions, including, in some instances, the possibility of exclusion from participation in federal and state health care 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 health care programs, private health insurers, managed health care 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 after approval as a benefit under their plans or, even if they do, 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 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 may be adversely affected if the

amount of payment for our products proves to be unprofitable for health care providers or less profitable than alternative treatments or if administrative burdens make our products less desirable to use.

Additionally, the containment of health care 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. Starting in 2023, 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, starting for payment year 2026, 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 and entered into the first set of agreements with pharmaceutical manufacturers to conduct price negotiations in October 2023. 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.

We expect that federal, state and local governments in the U.S. will continue to consider legislation directed at lowering the total cost of health care. Individual states in the United 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 health care 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 U.S. 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 health care 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 currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as 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 will be enacting new regulations and will have expanded enforcement authority. Moreover, various states such as Colorado, Connecticut, Delaware, Florida, Indiana, Iowa, Montana, Oregon, Tennessee, Texas, Utah and Virginia 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 health care professionals and other employees of foreign hospitals, clinics, research facilities and medical schools in countries with public health care or public education systems to be "foreign officials" under the FCPA. When we or our agents interact with foreign health care 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 U.S., 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 all of the risks associated with the FDA approval described above, 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 U.S., which requires the submission of a clinical trial application much like the IND prior to the commencement of clinical studies. In Europe, for example, a clinical trial application, or CTA, must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, 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 Authorisation Application, which is similar to the NDA, except that, among other things, there are country-specific document requirements. 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, some nations may not accept clinical studies performed for U.S. approval to support approval in their countries or require that additional studies be performed on natives of their countries. 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. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable the Clinical Trials Regulation will at that time begin to apply to the clinical trial.

The new 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. There continue to be challenges related to the implementation and use of the new CTIS by clinical researchers and trial sponsors.

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 certain diseases. For products with a new active substance indicated for the treatment of certain diseases and products that are highly innovative or for which a centralized process is not in the interest of patients, the centralized procedure may be optional. 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 a 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 of 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 labelling 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 five years 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 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 health care 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, which will revise and replace the existing general pharmaceutical legislation. 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

The United Kingdom ("UK") left the European Union on January 31, 2020 (commonly referred to as "Brexit"), with a transitional period that expired on December 31, 2020. The United Kingdom and the EU entered into a trade agreement known as the Trade and Cooperation Agreement, which went into effect on January 1, 2021. As a result, UK licensing decisions were transferred from the EMA to the Medicines and Healthcare Products Regulatory Agency ("MHRA"), the UK regulatory body responsible for overseeing medical products. For a period of three years following January 1, 2021, the UK will continue to adopt decisions taken by the European Commission on the approval of new marketing authorizations. However, companies will be required to submit an identical application to the MHRA upon the CHMP positive opinion of the application. The MHRA will then wait for the European Commission decision on approval.

More recently, in March 2023, the UK 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 expected to apply as of January 1, 2025 and will change the existing system under the Northern Ireland Protocol, including the regulation of pharmaceutical products in the UK. Specifically, the MHRA will be responsible for approving all medicines intended to be marketed in the UK (i.e., Great Britain and Northern Ireland), while the EMA will no longer be involved in approving medicines intended for sale in Northern Ireland.

Since the regulatory framework in the United Kingdom covering the quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from European Union directives and regulations, the ongoing transition could materially impact the future regulatory regime as it applies to medicinal products and the approval of our product candidates in the United Kingdom.

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.

- 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 one or more of our product development programs, and our business will consequently be harmed.
- We are substantially dependent on our lead product candidate, LSTA1. If we are unable to advance LSTA1 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 be unable to manage multiple late-stage clinical trials for a variety of product candidates simultaneously.
- 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 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 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 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 of our organization, and may experience difficulties in managing this growth.
- We are involved in a litigation matter that may consume resources and management time, and an adverse resolution could require us to pay damages or otherwise adversely impact our business, financial condition or results of operations.
- 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.
- 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 significant 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 will 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 likely 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 varying 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.
- Health care 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 health care costs may adversely affect our business.
- Inadequate funding for the FDA, the SEC and other government agencies could 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.
- 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.
- 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 impacted.
- Future fundraising and strategic transactions may cause dilution, and we currently have a significant number of 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.

HUMAN CAPITAL RESOURCES

As of December 31, 2023, we had 25 full-time employees. Senior management and professional employees have had prior experience in pharmaceutical 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 increase 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 have offices 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 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.

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 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, 2023, we have incurred aggregate net losses of approximately $528.1 million. Our net losses from continuing operations attributable to common stockholders for the years ended December 31, 2023 and December 31, 2022 were approximately $20.8 million and $54.2 million, respectively. As of December 31, 2023, our cash and cash equivalents and marketable securities were $50.5 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 one or more of our product development programs, and our business will be 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.

Our clinical activities are expected to continue to grow as our programs are advanced and they will require significant investment over a period of several years before they could potentially be approved by health authorities and commercialized by us or a partner, if ever. Even if data from our current clinical trials for our product candidates were deemed positive, we may 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 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:

- the scope, progress, results, costs, timing and outcomes of our research and development programs and product candidates;
- 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, we would likely seek to raise 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 will 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 could adversely affect our business, results of operations and financial condition.

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 and scalable 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 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 revenue from the sale of any approved products, we may never become profitable.

We are involved in a litigation matter that may consume resources and management time, and an adverse resolution could require us to pay damages or otherwise adversely impact our business, financial condition or results of operations.

We are currently involved in one litigation matter alleging breach of contract and fraud against our acquired company, Cend, and by extension now Lisata. Resolving this matter could require us to incur substantial costs and divert the attention of management and technical personnel. Any adverse ruling or perception of an adverse ruling could have an adverse impact on

our business, financial condition or results of operations. We could incur substantial costs and expenses which could negatively affect our gross margins and earnings per share.

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.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and its financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, or SVB, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership.

The U.S. Department of Treasury, FDIC and Federal Reserve Board announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. There is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity

constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- Loss of access to revolving existing credit facilities or other working capital sources and/or the inability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources;
- Potential or actual breach of contractual obligations that require us to maintain letters or credit or other credit support arrangements; or
- Termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by parties with whom we conduct business, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, a party with whom we conduct business may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy. Any bankruptcy or insolvency, or the failure to make payments when due, of any counterparty of ours, or the loss of any significant relationships, could result in material losses to us and may have material adverse impacts on our business.

RISKS RELATED TO OUR PRODUCT DEVELOPMENT EFFORTS

We are substantially dependent on our lead product candidate, LSTA1. If we are unable to advance LSTA1 or any of our future product candidates through clinical development, obtain regulatory approval and ultimately commercialize LSTA1 or any of our other product candidates, or experience significant delays in doing so, our business will be materially harmed.

Our lead product candidate LSTA1 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 LSTA1 and potentially one or more of our other product candidates. The success of our product candidates will depend on several 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 current or 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 lead product candidate, LSTA1, may also impact our ability to obtain regulatory approval for certain of our other product candidates, either at all or within anticipated timeframes because, although certain of our other product candidates may target different indications, the underlying technology platform, manufacturing process and development process is the same for several of our product candidates that are based on the same underlying technology platform. Accordingly, a failure in any one program may affect the ability to obtain regulatory approval to continue or conduct clinical programs for other product candidates. For example, although we believe based on our clinical studies that a combination of LSTA1 with certain anti-cancer therapeutics is more effective than the use of those therapeutics in alone, this may not prove true in clinical testing of LSTA1 for all or any of the types of cancer. Anti-tumor activity may prove different in each of the different tumor types we plan on evaluating. Therefore, even though we plan on pursuing tumor-agnostic clinical development of LSTA1, the tumor response may be less robust in patients with some cancers compared to others. This may result in discontinuation of development of LSTA1 for certain tumor types due to insufficient clinical benefit while continuing development for patients more likely to benefit. As a consequence, we may have to negotiate with regulators to reach agreement on defining the optimal patient population, study design and size in order to obtain regulatory approval, any of which may require significant additional resources and delay the timing of our clinical trials and ultimately the approval, if any, of any of our product candidates.

In addition, because we have limited financial and personnel resources and are placing significant focus on the development of our lead 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 significantly 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, difficult to design and implement, and can take many years to complete. Importantly, a failure of one or more of these or any other 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, implementation or completion of required clinical

trials;

- adverse changes in our financial position or significant and unexpected increases in the cost of our clinical development program;
- 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 could 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 or in a form 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 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 IRB 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 clinical trial operations or clinical trial sites; developments on trials conducted by competitors or approved products post-market for related technology that raises 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 and investigators;
- failure by our CROs, CMOs other third parties, or us to adhere to clinical trial requirements;
- 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;
- 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 our academic collaborators to larger-scale facilities operated by either a CMO, or by us, and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process;
- 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 is potentially different from the United States.

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 before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

The impact of the COVID-19 pandemic or as yet identified pandemics, the shift to a COVID-19 endemic approach and related risks could materially affect our results of operations, financial position and/or liquidity.

The COVID-19 pandemic resulted in a global slowdown of economic activity and disruption of normal business travel and working habits. While we are shifting to a COVID-19 endemic approach, there is still uncertainty about the impact of COVID-19 variants in the long-term. The COVID-19 pandemic may have impacted our results of operations, and a reversion to the COVID-19 restrictions could have a significant effect on our future business, results of operations and financial performance. The pandemic initially resulted in a sharp contraction in the global economy, tightening liquidity and increasing volatility and uncertainty in the capital markets. Coincident global mitigation responses stabilized markets and stimulated economic recovery. Continued macroeconomic volatility may persist affecting our businesses and related market opportunities. The impact of an ongoing pandemic on the financial markets may also adversely affect our ability to fund through public or private equity offerings, debt financings, and through other means at acceptable terms.

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 may 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 for 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 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 could 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. 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 foreign destinations within the expiry period of such materials unless and until we commence operation outside of the United States or find another source of supply.

Because our clinical trials for LSTA1 are focused on patients with specific solid tumor cancers, 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 will have each of the solid tumor cancers that LSTA1 is designed to target or that the number of patients enrolled will suffice for regulatory approval and inclusion of each such mutation in the approved label.

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

- size of the target patient population;
- severity of the disease or disorder under investigation;

- eligibility criteria for the clinical trial in question;
- other clinical trials being conducted at the same time involving patients who have 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.

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 LSTA1 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 submission of an 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 utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our 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:

- we may encounter unforeseeable conditions, such as the COVID-19 pandemic, which had a significantly negative impact on enrollment in clinical trials during its acute phase but may continue to create challenges if local or regional outbreaks occur;
- 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 REMS plan 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 such 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 the affected product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and significantly impact our ability to successfully commercialize our product candidates and generate revenues.

We and our partners are conducting clinical trials for product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We have in the past conducted clinical trials in Japan, and we may in the future choose to conduct one or more clinical trials outside the United States, including in Canada, Australia, or Europe. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are agreed by FDA to be applicable to the U.S. population and U.S. medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP requirements. For example, in February 2022, the FDA publicly rebuked an oncology product sponsor for submitting a marketing application with Phase III clinical data solely from China and since that time, it has declined to approve other applications that contained primarily China-generated clinical data. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of their applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in product candidates that we may 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 (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 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, material or equipment we are using in the clinical development of our product candidates could 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 safety and identity of our product candidates when administered to patients. If we determine that the results of any Phase 2 clinical trial, we may conduct supports 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 control ("CMC") issues raised by the FDA prior to initiating such trials. We may not be successful in our efforts to address any CMC issues raised by the FDA. 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 the FDA's CMC concerns or otherwise, 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 or 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, may not lead to 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 LSTA1 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 a 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 LSTA1 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 may not lead to 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 LSTA1 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 approval by the FDA, even if granted for LSTA1 or future product candidates, may not lead to 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 plan to seek approval of LSTA1 and may seek approval of other current or future product candidates using the FDA's accelerated approval pathway. A product candidate may be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. FDA may require that such studies be fully enrolled before the NDA is approved. These confirmatory trials must be completed with due diligence.

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. In addition, all promotional materials for products approved under the accelerated approval pathway must be submitted 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 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 approval does not provide assurance of ultimate full FDA 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 government 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 these factors and may include adequate duration of response, a delay in the progression of the disease, and/or an improvement in survival. For example, response rates from the use of our product candidates may not be sufficient to obtain regulatory approval unless we can also show an adequate duration of response.

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. A number of companies in the biopharmaceutical industry have suffered 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 the 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 recently announced the imposition of 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, 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 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 covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such 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 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.

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.

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 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 similar product candidates. 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 health care markets. If we ultimately obtain regulatory approval for any of our product candidates, we also will 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 resources being even more 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 Australian wholly-owned 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 and limited employees currently in Australia, as well as our limited of 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 that it conducts for our product candidates in Australia will be accepted by the FDA or 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, employees and intellectual property 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. None of our product candidates have been widely used over an extended period of time, and therefore relevant safety data are limited.

We will need to increase our insurance coverage when we begin commercializing product candidates, if ever. 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 could 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 operations, 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. 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 inaccurately calculate or lose our data. 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, 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 our third-party provider 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. 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.

Social media is increasingly being used to communicate information about clinical-stage oncology 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

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.

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

We currently have minimal manufacturing contracts to produce materials for our clinical trials. It is possible that the 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 expand, 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 late-stage 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 product candidates, if approved.

We do not currently own any facility that may be used as our 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 product candidates 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 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 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:

- differing regulatory requirements in foreign countries, for example, no country other than the United States has a pathway for accelerated drug approval and so obtaining regulatory approvals outside of the United States will take longer and be more costly than obtaining approval in the United States;
- 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.

The CendR Platform® may not become broadly accepted by 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 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;
- the prevalence and severity of any side effects for other precision medicines and public perception of other precision medicines;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by 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 government authorities;

- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities;
- 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 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, and the failure to receive regulatory approvals for our product candidates would likely have a material and adverse effect on our business and prospects.

Government 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 LSTA1. 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 LSTA1 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 not 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 potentially 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 with our product candidates.

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS in order to approve our product candidates, 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 product candidates 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, for any clinical trials that we conduct post-approval. 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 product candidates, 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;
- 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, if approved. 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 health care laws and regulations. Failure to comply with such biopharmaceutical and health care 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 health care 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 records and documentation for certain products. 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 exposing 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 introduces 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: comply with the regulations of the FDA and foreign regulatory authorities, provide true, complete and accurate information to the FDA and foreign regulatory authorities, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products, 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 health care 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 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 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 it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

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 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.

Health care 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 health care 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 health care 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 health care-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 health care 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 health care 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 health care industry, government and private payors may adopt strategies designed to limit the amount of reimbursement paid to health care providers.

Similarly, the trend toward managed health care and bundled pricing for health care services in the United States, could significantly influence the purchase of health care 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 health care programs, such as Medicare, and we may also directly or indirectly receive revenues from federal health care programs. Federal health care 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 health care reform favors the reimbursement of other therapies over our therapeutic products under development, such reform could affect our ability to sell our services, 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 health care 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, there has been a trend in recent years towards reductions in overall funding for Medicare and Medicaid. There has also been an increase in the number of people who do not have any form of health care coverage in recent years and who are not eligible for or enrolled in Medicare, Medicaid or other governmental programs. The extent to which the reforms brought about under health care 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 services to the extent they relate to products and services which are 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 the 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 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 it commercializes 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 it receives 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 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 health care costs may adversely affect our business.

The containment of health care 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 U.S. will continue to consider legislation directed at lowering the total cost of health care and prescription drugs. Individual states in the U.S. 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 health care 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 U.S. may affect the entire pharmaceutical supply chain and the business of other stakeholders, including medical product developers like us.

The Biden Administration has also indicated that lowering prescription drug prices is a priority, and on August 16, 2022, President Biden signed into the law the 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. Starting in 2023, 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, starting for payment year 2026, CMS will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar 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 and entered into the first set of agreements with pharmaceutical manufacturers to conduct price negotiations in October 2023. However, the IRA's impact on the biopharmaceutical industry in the U.S. 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.

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 health care 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 by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. 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.

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, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, 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;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad, including as a result of pandemics or the military actions involving Russia and Ukraine and the ongoing conflict in Israel and Gaza; 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 file patent applications, and have been issued patents, that are intended to cover certain methods and uses of human cells as well as compositions and methods relating to hematopoietic stem cells. These patent applications may never result in the issuance of patents.

The patent positions of biotechnology companies 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 can we 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 or 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 LSTA1. 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 LSTA1, 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 LSTA1, 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 it needs 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 nor 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 three pending patent applications in the United States and fourteen 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 intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

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 with the FDA's and other regulatory authority's cGMP regulations and guidelines. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our 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 of our organization, and may experience difficulties in managing this growth.

As of December 31, 2023, we had 25 full-time employees. We intend to hire new employees to conduct our research and development activities/administrative/scientific 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, maintaining and motivating additional employees;
- advance 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
- 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 management 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;
- 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; and
- a decline in share price.

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 our 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 cyber-attacks 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 CAPITAL 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, 2023 through February 29, 2024 our common stock traded as low as $1.95 per share and as high as $4.53 per share.

The market price for our common stock is highly dependent on, among other things, stock market conditions in general, 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. 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:

- 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, negative clinical trial results or adverse regulatory decisions relating to our product candidates;
- adverse fluctuations in our revenues or operating results or financial results that otherwise fall below the market's expectations;
- disappointing developments concerning our product candidates;
- 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 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 significant numbers of 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, 2023, there were 8,149,897 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 2,893,000 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 more difficult the removal of management 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. This individual has over 29 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. The space is approximately 8,100 rentable square feet and the base monthly rent is approximately $15,900 through September 30, 2025. We have two five-year renewal options. We believe the total leased space at the Basking Ridge, New Jersey location is sufficient for the near future.

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.

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. Lingmed filed an

answer to Cend's response on July 11, 2022. At a Case Management Conference held on August 4, 2023, the Court set a trial date in the matter for August 2, 2024. The Company denies these allegations made by Lingmed and intends to vigorously defend itself.

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 February 29, 2024, there were approximately 292 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, 2023 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)	1,322,501	$10.81	615,052	(3)
Equity compensation plans not approved by security holders	0	—	0	
Total	1,322,501	$10.81	615,052	(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 major diseases. Our lead investigational product candidate, LSTA1, is designed to activate a novel uptake pathway that allows co-administered or tethered (i.e., molecularly bound) anti-cancer drugs to target and penetrate solid tumors more effectively. LSTA1 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 unlikely to be affected. LSTA1 also has the potential to modify the tumor microenvironment ("TME"), thereby making tumors more susceptible to immunotherapies and inhibiting the metastasis cascade (i.e., the spread of cancer to other parts of the body). We and our collaborators have amassed significant non-clinical data demonstrating enhanced delivery of a range of existing and emerging anti-cancer therapies, including chemotherapeutics, immunotherapies and RNA-based therapeutics. To date, LSTA1 has also demonstrated favorable safety, tolerability and activity in completed and ongoing clinical trials designed to enhance delivery of standard-of-care chemotherapy for pancreatic cancer. We are exploring the potential of LSTA1 to enable a variety of treatment modalities to treat a range of solid tumors more effectively. Currently, LSTA1, is the subject of Phase 2a and 2b clinical studies being conducted globally in a variety of solid tumor types, including metastatic pancreatic ductal adenocarcinoma (mPDAC), cholangiocarcinoma, head and neck cancer, appendiceal cancer, colon cancer and glioblastoma multiforme in combination with a variety of anti-cancer regimens.

Our legacy CD34+ cell therapy technology was the subject of several clinical trials targeting an array of diseases, among them, critical limb ischemia, coronary microvascular dysfunction, and diabetic kidney disease. Further development of such programs would require significantly larger studies and capital investment and thus, development by Lisata would only be continued if a strategic partner that can contribute the necessary capital for future development is identified.

Our leadership team has 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.

Results of Operations

Year Ended December 31, 2023 Compared to Year Ended December 31, 2022

The following table summarizes our results of operations for the years ended December 31, 2023 and 2022:

	Year Ended December 31,		
	2023	2022	Change
Operating Expenses:			
Research and development	$ 12,734	$ 13,067	$ (333)
In-process research and development	—	30,393	(30,393)
General and administrative	12,974	14,141	(1,167)
Total operating expenses	25,708	57,601	(31,893)
Loss from operations	(25,708)	(57,601)	31,893
Total other income	2,538	897	1,641
Benefit from income taxes	(2,330)	(2,479)	(149)
Net loss	$ (20,840)	$ (54,225)	$ 33,385

Overall, net losses were $20.8 million and $54.2 million for the years ended December 31, 2023 and 2022, respectively.

Operating Expenses

For the year ended December 31, 2023, operating expenses totaled $25.7 million compared to $57.6 million for the year ended December 31, 2022, representing a decrease of $31.9 million or 55.4%. Excluding the in-process research and development expense of $30.4 million associated with the Merger, operating expenses decreased by $1.5 million or 5.5% compared to the year ended December 31, 2022.

Operating expenses comprise the following:

- Research and development expenses were approximately $12.7 million for the year ended December 31, 2023 compared to $13.1 million for the year ended December 31, 2022, representing a decrease of approximately $0.3 million, or 2.5%. This decrease was primarily due to lower costs associated with our LSTA1 programs in the current year versus our legacy CD34+ cell therapy technology programs in the prior year. Current year expenses were associated with study activities for LSTA1 Phase 2a proof-of-concept Bolster trial in various solid tumors in combination with the corresponding standards of care, enrollment activities for the LSTA1 Phase 2b ASCEND study, chemistry, manufacturing and control ("CMC") activities for LSTA1 and study start up activities for the LSTA1 Phase 2a study for the treatment of glioblastoma multiforme.

- General and administrative expenses were approximately $13.0 million for the year ended December 31, 2023, compared to $14.1 million for the year ended December 31, 2022, representing a decrease of approximately $1.2 million or 8.3%. This decrease was primarily due to non-recurring Merger related costs in the prior year, a decrease in equity expense due to prior year performance stock unit vesting, Merger option assumption expense and departing board member restricted stock unit vesting, lower annual stockholder meeting expenses and a decrease in directors and officers insurance premiums, partially offset by severance costs associated with the elimination of the Chief Business Officer position on May 1, 2023.

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 is comprised primarily of investment income on cash, cash equivalents and marketable securities and a loss on sale related to the sale of our New Jersey net operating losses ("NJ NOLs").

Income Tax Benefit

In April 2023, we received final approval from the New Jersey Economic Development Authority ("NJEDA") under the Technology Business Tax Certificate Transfer Program ("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 $2.2 million. The $2.3 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 February 2022, 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 $2.3 million. The $2.5 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, 2023, we had cash, cash equivalents, and marketable securities of approximately $50.5 million, working capital of approximately $47.3 million, and stockholders' equity of approximately $48.1 million.

During the year ended December 31, 2023, 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,	
	2023	2022
Net cash used in operating activities	$ (20,032)	$ (21,170)
Net cash provided by investing activities	10,102	28,911
Net cash provided by (used in) financing activities	385	(224)

Operating Activities

Our cash used in operating activities during the year ended December 31, 2023 totaled approximately $20.0 million, comprising (i) our net loss of $20.8 million, as adjusted for non-cash income and expenses totaling $1.3 million (which includes adjustments for equity-based compensation, depreciation and amortization, and amortization/accretion of marketable securities), and (ii) changes in operating assets and liabilities of approximately $0.5 million.

Our cash used in operating activities during the year ended December 31, 2022 totaled approximately $21.2 million, comprising (i) our net loss of $54.2 million, as adjusted for non-cash income and expenses totaling $33.9 million (which includes adjustments for equity-based compensation, depreciation and amortization, in process research and development expenses, and amortization/accretion of marketable securities), and (ii) changes in operating assets and liabilities of approximately $0.8 million.

Investing Activities

Our cash provided by investing activities during the year ended December 31, 2023 totaled approximately $10.1 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, 2022 totaled approximately $28.9 million and was primarily due to net sales of marketable securities (net of purchases of marketable securities) and partially offset by asset acquisition costs, net of cash acquired related to the Merger of $3.3 million.

Financing Activities

Our cash provided by financing activities during the year ended December 31, 2023 totaled $0.4 million, consisting of proceeds from the issuance of shares through our ATM Agreement (as defined below) of $0.3 million, option exercise proceeds of $0.2 million partially offset by tax withholding-related payments of $0.1 million on net share settlement equity awards to employees.

Our cash used in financing activities during the year ended December 31, 2022 totaled $0.2 million, consisting primarily of tax withholding-related payments on net share settlement equity awards to employees.

Liquidity and Capital Requirements Outlook

To meet our short and long-term liquidity needs, we expect to use existing cash balances, marketable securities 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. We believe that our cash on hand and marketable securities will enable us to fund operating expenses for at least the next 12 months following the issuance of our financial statements. Our future capital requirements are difficult to forecast and will depend on many factors, including the timing and nature of 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 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 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. Subsequent to the filing of our Form 10-K on March 22, 2022, the aggregate market value of our outstanding common stock held by non-affiliates was approximately $43.6 million. Pursuant to General Instruction I.B.6 of Form S-3, since the aggregate market value of our outstanding common

stock held by non-affiliates was below $75.0 million at the time of such Form 10-K filing, the aggregate amount of securities that we are permitted to offer and sell was reduced to $17,698,943, which was equal to one-third of the aggregate market value of our common stock held by non-affiliates as of September 21, 2022. As of December 31, 2023, we issued 64,394 shares of common stock under the ATM Agreement for net proceeds of $270,774 under the ATM Agreement.

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.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

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.

Merger with Cend Therapeutics

On September 15, 2022, we, then operating as Caladrius, completed the Merger in accordance with the terms of the Merger Agreement. We concluded that the Merger was an asset acquisition, as substantially all of the fair value of the non-monetary assets acquired was concentrated in IPR&D. We determined that the cost to acquire the Cend assets was $36.1 million, based on the fair value of the equity consideration issued, our initial investment, assumption of stock options and direct costs of the acquisition. The net assets acquired in connection with the Merger were recorded at their estimated fair values as of September 15, 2022, which was the date Merger was completed. Cend's assets (except for cash and working capital) were measured and recognized as an allocation of the transaction price based on their relative fair values as of the transaction date with any value associated with IPR&D with no alternative future use being expensed as reported in the consolidated statement of operations.

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. Consultant awards are remeasured each reporting period through vesting. 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. 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

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders of 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, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, equity, and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Basis for opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

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
February 29, 2024

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

	December 31, 2023	December 31, 2022
ASSETS		
Current Assets		
Cash and cash equivalents	$ 22,593	$ 32,154
Marketable securities	27,942	37,072
Prepaid and other current assets	3,389	2,650
Total current assets	53,924	71,876
Property and equipment, net	175	296
Acquired license-intangible, net	263	334
Other assets	332	528
Total assets	$ 54,694	$ 73,034
LIABILITIES, NON-CONTROLLING INTERESTS AND STOCKHOLDERS' EQUITY		
Liabilities		
Accounts payable	$ 2,421	$ 2,655
Accrued liabilities	4,169	3,728
Total current liabilities	6,590	6,383
Other long-term liabilities	210	327
Total liabilities	6,800	6,710
Commitments and Contingencies (Note 14)		
Stockholders' Equity		
Common stock, $0.001 par value, authorized 33,333,333 shares; issued 8,150,635 and 7,866,799 shares, at December 31, 2023 and December 31, 2022, respectively; and outstanding, 8,149,897 and 7,866,061 shares, at December 31, 2023 and December 31, 2022, respectively	8	8
Additional paid-in capital	576,971	574,548
Treasury stock, at cost; 738 shares at December 31, 2023 and December 31, 2022 respectively	(708)	(708)
Accumulated deficit	(528,081)	(507,241)
Accumulated other comprehensive loss	(42)	(29)
Total Lisata Therapeutics, Inc. stockholders' equity	48,148	66,578
Non-controlling interests	(254)	(254)
Total equity	47,894	66,324
Total liabilities, non-controlling interests and stockholders' equity	$ 54,694	$ 73,034

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,	
	2023	**2022**
Operating Expenses:		
Research and development	$ 12,734	$ 13,067
In-process research and development	—	30,393
General and administrative	12,974	14,141
Operating expenses	25,708	57,601
Operating loss	(25,708)	(57,601)
Other income (expense):		
Investment income, net	2,724	1,052
Other expense, net	(186)	(155)
Total other income	2,538	897
Net loss before benefit from income taxes and noncontrolling interests	(23,170)	(56,704)
Benefit from income taxes	(2,330)	(2,479)
Net loss	$ (20,840)	$ (54,225)
Less - net income (loss) attributable to noncontrolling interests	—	—
Net loss attributable to Lisata Therapeutics, Inc. common stockholders	$ (20,840)	$ (54,225)
Basic and diluted loss per share:		
Lisata Therapeutics, Inc. common stockholders	$ (2.58)	$ (10.47)
Weighted average common shares outstanding:		
Basic and diluted shares	8,073	5,180

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,	
	2023	**2022**
Net loss	$ (20,840)	$ (54,225)
Other comprehensive income (loss):		
Available for sale securities - net unrealized gain	12	52
Cumulative translation adjustment arising during the period	(25)	(11)
Total other comprehensive income (loss)	(13)	41
Comprehensive loss	(20,853)	(54,184)
Comprehensive income (loss) attributable to noncontrolling interests	—	—
Comprehensive loss attributable to Lisata Therapeutics, Inc. common stockholders	$ (20,853)	$ (54,184)

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, 2021	3,986	$ 4	$ 546,044	$ (70)	$ (453,016)	$ (708)	$ 92,254	$ (254)	$ 92,000
Net loss	—	—	—	—	(54,225)	—	(54,225)	—	(54,225)
Share-based compensation	97	—	2,367	—	—	—	2,367	—	2,367
Net proceeds from issuance of common stock	11	—	43	—	—	—	43	—	43
Issuance of common stock in connection with Merger	3,773	4	26,094	—	—	—	26,098	—	26,098
Unrealized gain on marketable securities	—	—	—	52	—	—	52	—	52
Foreign currency translation adjustment	—	—	—	(11)	—	—	(11)	—	(11)
Balance at December 31, 2022	7,867	$ 8	$ 574,548	$ (29)	$ (507,241)	$ (708)	$ 66,578	$ (254)	$ 66,324
Net loss	—	—	—	—	(20,840)	—	(20,840)	—	(20,840)
Share-based compensation	114	—	1,947	—	—	—	1,947	—	1,947
Net proceeds from issuance of common stock	87	—	321	—	—	—	321	—	321
Proceeds from option exercises	83	—	155		—	—	155	—	155
Unrealized gain on marketable securities	—	—	—	12	—	—	12	—	12
Foreign currency translation adjustment	—	—	—	(25)	—	—	(25)	—	(25)
Balance at December 31, 2023	8,151	$ 8	$ 576,971	$ (42)	$ (528,081)	$ (708)	$ 48,148	$ (254)	$ 47,894

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (20,840)	$ (54,225)
Adjustments to reconcile net loss to net cash used in operating activities:		
Equity-based compensation expense	2,038	2,636
Depreciation and amortization	189	69
Loss on disposal of fixed assets	3	—
In-process research and development expenses	—	30,393
Amortization/accretion on marketable securities	(960)	788
Changes in operating assets and liabilities:		
Prepaid and other current assets	(824)	(845)
Other assets	274	237
Accounts payable, accrued liabilities and other liabilities	88	(223)
Net cash used in operating activities	(20,032)	(21,170)
Cash flows from investing activities:		
Purchase of marketable securities	(98,479)	(89,687)
Sales of marketable securities	108,581	122,203
Asset acquisition costs, net of cash acquired related to Merger	—	(3,320)
Purchases of property and equipment	—	(285)
Net cash provided by investing activities	10,102	28,911
Cash flows from financing activities:		
Proceeds from exercise of options	155	—
Tax withholding payments on net share settlement equity awards	(91)	(267)
Net proceeds from issuance of capital stock	321	43
Net cash provided by (used in) financing activities	385	(224)
Effect of exchange rate changes on cash	(16)	(10)
Net (decrease) increase in cash and cash equivalents	(9,561)	7,507
Cash and cash equivalents at beginning of year	32,154	24,647
Cash and cash equivalents at end of year	$ 22,593	$ 32,154
Supplemental Disclosure of Cash Flow Information:		
Issuance of common stock in connection with Merger	$ —	$ 23,580
Incremental fair value of Cend's fully vested stock options assumed	$ —	$ 2,136

See accompanying notes to consolidated financial statements.

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

Note 1 – The 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 major diseases. The Company's lead investigational product candidate, LSTA1, is designed to activate a novel uptake pathway that allows co-administered or tethered (i.e., molecularly bound) anti-cancer drugs to target and penetrate solid tumors more effectively. LSTA1 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 unlikely to be affected. LSTA1 also has the potential to modify the tumor microenvironment ("TME"), thereby making tumors more susceptible to immunotherapies and inhibiting the metastasis cascade (i.e., the spread of cancer to other parts of the body). The Company and its collaborators have amassed significant non-clinical data demonstrating enhanced delivery of a range of existing and emerging anti-cancer therapies, including chemotherapeutics, immunotherapies and RNA-based therapeutics. To date, LSTA1 has also demonstrated favorable safety, tolerability and activity in completed and ongoing clinical trials designed to enhance delivery of standard-of-care chemotherapy for pancreatic cancer. The Company is exploring the potential of LSTA1 to enable a variety of treatment modalities to treat a range of solid tumors more effectively. Currently, LSTA1, is the subject of Phase 2a and 2b clinical studies being conducted globally in a variety of solid tumor types, including metastatic pancreatic ductal adenocarcinoma (mPDAC), cholangiocarcinoma, head and neck cancer, appendiceal cancer, colon cancer and glioblastoma multiforme in combination with a variety of anti-cancer regimens.

The Company's legacy CD34+ cell therapy technology was the subject of several clinical trials targeting an array of diseases, among them, critical limb ischemia, coronary microvascular dysfunction, and diabetic kidney disease. Further development of such programs would require significantly larger studies and capital investment and thus, development by Lisata would only be continued if a strategic partner that can contribute the necessary capital for future development is identified.

The Company's leadership team has 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.

Merger with Cend Therapeutics, Inc. and Name Change

On September 15, 2022, the Company, then operating as Caladrius Biosciences, Inc. ("Caladrius"), completed its acquisition of Cend Therapeutics, Inc. ("Cend"), a Delaware corporation (the "Merger"), in accordance with the terms of the Agreement and Plan of Merger and Reorganization (the "Merger Agreement"), dated as of April 26, 2022, by and among Caladrius, Cend and CS Cedar Merger Sub, Inc. ("Merger Sub").

Pursuant to the terms set forth in the Merger Agreement and effective September 15, 2022 (the "Effective Time"): (i) Merger Sub merged with and into Cend, with Cend surviving as a wholly owned subsidiary of Caladrius, (ii) Caladrius changed its name to Lisata Therapeutics, Inc., and (iii) Caladrius effected a 1:15 reverse stock split of its common stock ("Reverse Stock Split") prior to the Effective Time. At the Effective Time, each share of Cend's common stock outstanding immediately prior to the Effective Time was converted into the right to receive shares of Lisata's common stock based on an exchange ratio of 0.5338, after taking into account the Reverse Stock Split (the "Exchange Ratio"). In connection with the Merger close, the Company issued an aggregate of 3,772,768 shares of common stock, based on the Exchange Ratio, to holders of Cend, in exchange for all of the Cend capital stock outstanding immediately prior to the closing of the Merger.

Pursuant to the Merger Agreement, Lisata assumed all of the outstanding and unexercised options to purchase shares of Cend capital stock under the 2016 Equity Incentive Plan (the "Cend Plan"), and, in connection with the Merger, such options were converted into options to purchase shares of Lisata's common stock based on the Exchange Ratio. At the closing of the Merger at the Effective Time, the Company assumed Cend's stock options to purchase an aggregate of 1,227,776 shares of the Company's common stock.

Caladrius was considered to be the accounting acquirer based on the terms of the Merger Agreement and certain factors including: (i) Caladrius owned approximately 52% of the Company's outstanding shares of common stock immediately following the close of the Merger; (ii) although both entities contributed to the new management team of Lisata, the Caladrius team provided a vast majority of the individuals on the management team and holds the chief executive officer ("CEO"), chief

medical officer (“CMO”) and other senior management roles; (iii) Caladrius paid a premium to acquire Cend’s assets; and (iv) Caladrius was significantly larger than Cend regarding total assets, operations, and research and development activities. The Merger was accounted for as an asset acquisition as substantially all of the fair value is concentrated in in-process research and development (“IPR&D”). Cend’s assets (except for cash and working capital) were measured and recognized as an allocation of the transaction price based on their relative fair values as of the transaction date with any value associated with IPR&D with no alternative future use being expensed as reported in the consolidated statement of operations. Operating results presented in the consolidated statements of operations and comprehensive loss prior to the Merger are solely related to Caladrius Biosciences, Inc. and subsidiaries.

Reverse Stock Split

On September 14, 2022, in connection with the Merger, the Company implemented the Reverse Stock Split, as authorized at the annual meeting of stockholders on September 13, 2022. The Reverse Stock Split became effective on September 14, 2022 at 5:00 pm and the Company's common stock began trading on The Nasdaq Capital Market on a post-split basis at the open of business on September 15, 2022. As of September 14, 2022, every fifteen shares of the Company’s issued and outstanding common stock (and such shares held in treasury) were automatically converted into one share of common stock, without any change in the par value per share. In addition, proportionate adjustments were made to the per share exercise price and the number of shares issuable upon the exercise of all outstanding stock options, stock appreciation rights, convertible notes and warrants to purchase shares of common stock, the number of shares issuable upon the vesting of all restricted stock awards, and the number of shares of common stock reserved for issuance pursuant to the Company’s equity incentive compensation plans. Any stockholder who would otherwise be entitled to a fractional share of common stock created as a result of the Reverse Stock Split received a cash payment equal to the product of such resulting fractional interest in one share of common stock multiplied by the closing trading price of the common stock on September 15, 2022. The Reverse Stock Split was effectuated in order to increase the per share trading price of the Company's common stock to satisfy the $1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market.

All share and per share amounts of common stock, options and warrants in the accompanying financial statements have been restated for all periods presented to give retroactive effect to the Reverse Stock Split. Accordingly, the consolidated statements of equity reflect the impact of the Reverse Stock Split by reclassifying from “common stock” to “additional paid-in capital” in an amount equal to the par value of the decreased shares resulting from the Reverse Stock Split.

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”).

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 and the valuation of the Merger, which was accounted for as an asset acquisition as substantially all of the fair value is concentrated in in-process research and development (“IPR&D”). Accordingly, actual results could differ from those estimates and assumptions.

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.

Note 2 – Summary of Significant Accounting Policies

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 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. Cash is held at major banks in the United States and may exceed federally insured limits. 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.

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 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 other-than-temporary declines in the fair value of securities, 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	Life of lease

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. Consultant awards are remeasured each reporting period through vesting. 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. Stock 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 common shares 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 common shares used in the basic loss per share calculation plus the number of common shares 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 product candidate initiatives, the Company will continue targeting key governmental agencies, congressional committees 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, Cend's license agreement with Qilu Pharmaceutical, Co., Ltd. ("Qilu") acquired in the 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 $71 thousand and $21 thousand for the years ended December 31, 2023 and December 31, 2022, respectively. The intangible asset is reviewed for potential impairment when events or circumstances indicate that carrying amounts may not be recoverable. The projected amortization expense is $71 thousand per year for the next four years.

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. There was no revenue recognized for the years ended December 31, 2023 and 2022.

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, 2023 and 2022 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 – Merger

The Merger was accounted for as an asset acquisition as substantially all of the fair value was concentrated in IPR&D. Cend's assets (except for cash and working capital) were measured and recognized as an allocation of the transaction price based on their relative fair values as of the transaction date with any value associated with IPR&D being expensed. The fair value of total consideration was $36.1 million. The following table is a summary of the purchase price calculation (in thousands except per share data).

Number of common shares of the combined company owned by Cend stockholders	3,772,768
Multiplied by the fair value per share of Lisata common stock on September 15, 2022	$6.25
Total	$23,580
Carrying value of Lisata's cost method investment in Cend	10,000
Incremental fair value of Cend's fully vested stock options	2,136
Lisata transaction costs	382
Total purchase price	$36,098

The allocation of the purchase price was as follows (amounts in thousands):

Cash and cash equivalents	$7,062
Net working capital (excluding cash)	(1,690)
Other liabilities	(22)
Acquired in-process research and development	30,393
License	355
Net assets acquired	$36,098

Note 4 – 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, 2023				December 31, 2022			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities	$ 37,791	$ 3	$ (8)	$ 37,786	$ 44,308	$ —	$ (17)	$ 44,291
Commercial Paper	1,981	—	—	1,981	7,953	—	—	7,953
Money market funds	4,268	—	—	4,268	4,871	—	—	4,871
Municipal debt securities	622	—	—	622	7,626	—	(1)	7,625
Total	$ 44,662	$ 3	$ (8)	$ 44,657	$ 64,758	$ —	$ (18)	$ 64,740

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 debt securities on the Company's Consolidated Balance Sheets (in thousands):

	December 31, 2023	December 31, 2022
Cash and cash equivalents	$ 16,715	$ 27,668
Marketable securities	27,942	37,072
Total	$ 44,657	$ 64,740

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

	December 31, 2023		December 31, 2022	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Less than one year	$ 44,662	$ 44,657	$ 64,758	$ 64,740
Greater than one year	—	—	—	—
Total	$ 44,662	$ 44,657	$ 64,758	$ 64,740

Note 5 – Property and Equipment

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

	December 31,	
	2023	2022
Furniture and fixtures	$ —	$ 25
Computer equipment	589	589
Leasehold improvements	72	99
Property and equipment, gross	661	713
Accumulated depreciation	(486)	(417)
Property and equipment, net	$ 175	$ 296

The Company's results included depreciation expense of approximately $0.1 million and $0.1 million for the years ended December 31, 2023 and 2022, respectively.

Note 6 – Income (Loss) Per Share

For the years ended December 31, 2023 and 2022, the Company incurred net losses and therefore no common stock equivalents were utilized in the calculation of loss per share as they are anti-dilutive in the periods presented. At December 31, 2023 and 2022, the Company excluded the following potentially dilutive securities (in thousands):

	December 31,	
	2023	2022
Stock Options	1,323	1,391
Warrants	1,422	1,424
Restricted Stock Units	148	48

Note 7 – 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, 2023 and December 31, 2022 were as follows (in thousands):

	December 31, 2023				December 31, 2022			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Cash equivalents	$ 16,715	$ —	$ —	$ 16,715	$ 27,668	$ —	$ —	$ 27,668
Marketable securities - available for sale	—	27,942	—	27,942	—	37,072	—	37,072
	$ 16,715	$ 27,942	$ —	$ 44,657	$ 27,668	$ 37,072	$ —	$ 64,740

The carrying values of cash, cash equivalents, accounts payable and accrued expenses approximate fair value at December 31, 2023 and December 31, 2022, due to the short maturity nature of these items.

Note 8 – Accrued Liabilities

Accrued liabilities were as follow (in thousands):

	December 31,	
	2023	2022
Salaries, employee benefits and related taxes	$ 2,665	$ 2,586
Operating lease liabilities - current	168	180
Clinical and R&D related liabilities	1,046	785
Accounting and consulting	57	66
Other	233	111
	$ 4,169	$ 3,728

Note 9 – Operating Leases

The Company adopted ASU No. 2016-02, Leases (Topic 842) on January 1, 2019 and recognized leases with duration greater than 12 months on the balance sheet using the modified retrospective approach. The Company has an operating lease for one office which expires in 2025. The Company estimates its incremental borrowing rate at lease commencement to determine the present value of lease payments as most of the Company's leases do not provide an implicit rate of return. The Company recognizes lease expense on a straight-line basis over the lease term. For lease agreements entered into or reassessed after the adoption of 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 includes an option for the Company to extend the lease term and/or sub-lease space in whole or in part.

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, 2023	December 31, 2022
Right-of-Use Assets:		
Other assets	$ 308	$ 487
Total Right-of-Use Asset	$ 308	$ 487
Operating Lease Liabilities:		
Accrued liabilities	$ 168	$ 180
Other long-term liabilities	137	305
Total Operating Lease Liabilities	$ 305	$ 485

As of December 31, 2023, the weighted average remaining lease term for the Company's operating leases was 1.75 years, and the weighted average discount rate for its operating leases was 9.625%. Future minimum lease payments under the lease agreements as of December 31, 2023 were as follows (in thousands):

Years ended	Operating Leases
2024	190
2025	143
Total lease payments	333
Less: Amounts representing interest	(28)
Present value of lease liabilities	$ 305

Note 10 – Stockholders' Equity

Reverse Stock Split

On September 14, 2022, in connection with the Merger, the Company implemented the Reverse Stock Split, as described in Note 1. All share and per share amounts of common stock, options and warrants in the accompanying financial statements have been restated for all periods presented to give retroactive effect to the Reverse Stock Split. Accordingly, the consolidated statements of equity reflect the impact of the Reverse Stock Split by reclassifying from “common stock” to “additional paid-in capital” in an amount equal to the par value of the decreased shares resulting from the Reverse Stock Split.

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 June 2018, and subsequently increased by the stockholders of the Company in June 2023 with 400,000 shares authorized for issuance thereunder and in September 2022 with 333,333 shares authorized for issuance thereunder and in June 2021 with 400,000 shares authorized for issuance thereunder and in June of 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, 2023 and 2022 there were 593,141 shares and 578,097 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.

During the year ended December 31, 2023, 22,441 shares were issued under the Amended 2017 ESPP. At December 31, 2023 and 2022, the Company had 21,911 shares and 9,352 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. Subsequent to the filing of the Company's Form 10-K on March 22, 2022, the aggregate market value of its outstanding common stock held by non-affiliates was approximately $43.6 million. Pursuant to General Instruction I.B.6 of Form S-3, 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 Form 10-K filing, the aggregate amount of securities that the Company is permitted to offer and sell was reduced to $17,698,943, which was equal to one-third of the aggregate market value of the Company's common stock held by non-affiliates as of September 21, 2022. During the twelve months ended December 31, 2023, the Company issued 64,394 shares of common stock under the ATM Agreement for net proceeds of $270,774. Since inception, the Company has issued 64,394 shares of common stock under the ATM Agreement for net proceeds of $270,774.

Common Stock

In connection with the Merger closing on September 15, 2022, the Company issued an aggregate of 3,772,768 shares of common stock, based on the Exchange Ratio, to holders of Cend, in exchange for all of the Cend capital stock outstanding immediately prior to the closing of the Merger.

Stock Options and Warrants

In connection with the Merger and after giving effect to the Reverse Stock Split, the Company assumed 1,227,776 of Cend's outstanding options. The options granted under the Cend Plan are exercisable at various dates as determined upon grant and will expire no more than ten years from their original date of grant. The Cend Plan stock options generally vest over a four-year term. The following table summarizes the activity for stock options and warrants for the year ended December 31, 2023:

	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, 2022	1,391,352	$ 10.83	7.03	$ 187.6	1,423,774	$ 42.57	3.37	$ —
Changes during the Year:								
Granted	182,846	$ 3.45			—	—		
Exercised	(82,500)	$ 1.88			—	—		
Forfeited	(144,594)	$ 3.63			—	—		
Expired	(24,603)	$ 29.60			(2,000)	88.35		
Outstanding at December 31, 2023	1,322,501	$ 10.81	6.06	$ 164.1	1,421,744	$ 42.51	2.42	$ —
Vested at December 31, 2023 or expected to vest in the future	1,319,053	$ 10.83	6.05	$ 164.1	1,421,744	$ 42.51	2.42	$ —
Exercisable at December 31, 2023	1,229,103	$ 11.25	5.84	$ 159.9	1,421,744	$ 42.51	2.42	$ —

Restricted Stock

During the years ended December 31, 2023 and 2022, the Company issued restricted stock for services as follows ($ in thousands, except share data):

	2023	2022
Number of Restricted Stock Issued	159,950	70,740
Value of Restricted Stock Issued	$ 479.9	$ 973.4

The weighted average estimated fair value of restricted stock issued for services in the years ended December 31, 2023 and 2022 was $3.00 and $13.76 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 to four years.

The following is a summary of the changes in non-vested restricted stock for the year ended December 31, 2023:

	Restricted Stock Shares	Weighted Average Grant-Date Fair Value
Non-vested at December 31, 2022	56,209	$ 16.55
Changes during the Year:		
Granted	159,950	$ 3.00
Vested	(65,511)	$ 9.03
Forfeited	(24,873)	$ 3.28
Non-vested at December 31, 2023	125,775	$ 5.86

Restricted Stock Units

During the years ended December 31, 2023 and 2022, the Company issued restricted stock units for services as follows ($ in thousands, except share data):

	2023	2022
Number of Restricted Stock Units Issued	188,850	111,170
Value of Restricted Stock Units Issued	$ 566.6	$ 1,385.5

The weighted average estimated fair value of restricted stock units issued for services in the years ended December 31, 2023 and 2022 was $3.00 and $12.46 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, 2023:

	Restricted Stock Units	Weighted Average Grant-Date Fair Value
Non-vested at December 31, 2022	32,286	$ 9.29
Changes during the Year:		
Granted	188,850	$ 3.00
Vested	(29,486)	$ 8.48
Forfeited	(78,850)	$ 3.00
Non-vested at December 31, 2023	112,800	$ 3.37

Note 11 – Share-Based Compensation

Share-based Compensation

The Company utilizes share-based compensation in the form of stock options, restricted stock, and restricted stock units. The following table summarizes the components of share-based compensation expense for the years ended December 31, 2023 and 2022 ($ in thousands):

	Year Ended December 31,	
	2023	2022
Research and development	$ 540	$ 776
General and administrative	1,498	1,860
Total share-based compensation expense	$ 2,038	$ 2,636

The Company modified the exercise period of approximately 186,600 shares of one terminated employee's vested stock options and immediately recognized approximately $258 thousand incremental stock-based compensation during the year ended December 31, 2023.

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, 2023 were as follows ($ in thousands):

	Stock Options	Restricted Stock Units	Restricted Stock
Unrecognized compensation cost	$ 186	$ 76	$ 391
Expected weighted-average period in years of compensation cost to be recognized	1.70	1.55	1.53

Total fair value of shares vested and the weighted average estimated fair values of shares granted for the years ended December 31, 2023 and 2022 were as follows ($ in thousands):

	Stock Options	
	Year Ended December 31,	
	2023	2022
Total fair value of shares vested	$ 1,033	$ 1,045
Weighted average estimated fair value of shares granted	2.09	1.23

Valuation Assumptions

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

	Stock Options	
	Year Ended December 31,	
	2023	2022
Expected term - minimum (in years)	3	6
Expected term - maximum (in years)	6	6
Expected volatility - minimum	74%	76%
Expected volatility - maximum	77%	78%
Weighted Average volatility	75%	76%
Expected dividend yield	—	—
Risk-free interest rate - minimum	3.63%	1.62%
Risk-free interest rate - maximum	4.68%	2.90%

Note 12 – 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,	
Pre-tax book income	2023	2022
United States	$ (21,477)	$ (56,175)
Australia	(1,693)	(529)
Total	$ (23,170)	$ (56,704)

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

	Years Ended December 31,	
	2023	2022
Current		
U.S. Federal	$ —	$ —
State and local	—	—
	$ —	$ —
Deferred		
U.S. Federal	$ —	$ —
State and local	(2,330)	(2,479)
	$ (2,330)	$ (2,479)
Total		
U.S. Federal	$ —	$ —
State and local	(2,330)	(2,479)
	$ (2,330)	$ (2,479)

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,	
	2023	2022
U.S. Federal benefit at statutory rate	$ (4,865)	$ (11,908)
Permanent nondeductible expenses for U.S. taxes	875	7,238
Change in state deferred	809	8,604
Tax Return to Provision	(58)	(1)
Expired options	569	162
Other true ups	166	(25)
AUS Foreign Rate Differential	(22)	(21)
Section 382 NOL Limitation	—	18,553
Sale of New Jersey State NOLs	(2,330)	(2,479)
Valuation allowance for deferred tax assets	2,526	(22,602)
Tax benefit	$ (2,330)	$ (2,479)

Deferred income taxes at December 31, 2023 and 2022 consist of the following ($ in thousands):

	December 31,	
	2023	2022
Deferred Tax Assets:		
Accumulated net operating losses (tax effected)	$ 12,736	$ 13,132
Lease liability	86	136
Share-based compensation	2,370	3,027
Intangibles	889	944
Capitalized research and development	6,662	5,018
Accumulated depreciation	10	14
Accrued payroll	218	118
Other	638	579
Deferred tax assets	23,609	22,968
Deferred Tax Liabilities:		
Right-of-use asset	$ (87)	$ (137)
Cash to accrual	—	(99)
Deferred tax liabilities	(87)	(236)
Net deferred tax asset	23,522	22,732
Valuation allowance	(23,522)	(22,732)
Net deferred tax asset	$ —	$ —

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, 2023 and 2022, the Company had approximately $43.7 million and $33.7 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, $88.2 million of Federal NOLs will expire unutilized. The Company wrote off that portion of the deferred tax asset and reduced the corresponding valuation allowance resulting in $34.0 million of remaining Federal NOLs as of December 31, 2022. The write-off of the deferred tax asset and the corresponding reduction in valuation allowance has no impact to the consolidated balance sheet or income statement. Losses incurred before the ownership change on September 15, 2022 will be subject to an annual limitation of zero while losses incurred after September 15, 2022 will not be subject to limitations.

As of December 31, 2022, Cend Therapeutics 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, 2023 and 2022, Cend's wholly owned Australian subsidiary had approximately $2.4 million and $1.8 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, 2023, 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, 2023 and 2022, the Company had State NOLs available in New Jersey of $19.4 million and $35.5 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 2043. The usage of the Company's NOLs is limited given the change in ownership.

The Company applies the FASB's 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, 2023 and 2022, 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,	
	2023	2022
Gross unrecognized tax benefit, beginning of period	$ 344	$ —
Additions based on tax positions related to the current year	—	—
Additions based on tax positions related to the prior years	—	344
Reductions due to lapse in statute of limitations and settlements	—	—
Gross unrecognized tax benefit, end of period	$ 344	$ 344

For years prior to 2020 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.

In September 2022, 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 April 5, 2023, the Company received final approval from NJEDA to sell $25.9 million of its NJ NOLs, which were subsequently sold to a qualifying and approved buyer pursuant to the Program for net proceeds of $2.2 million. The gross proceeds from the sale of the $2.3 million NJ NOLs related tax benefits ("NJ NOL Tax Benefits"), have been recorded as a benefit from income taxes and the loss on sale of the NJ NOL Tax Benefits of $0.1 million recorded in other income (expense) in the consolidated financial statements.

On August 16, 2022, the Inflation Reduction Act was signed into law. The Inflation Reduction Act includes various tax provisions, which are effective for tax years beginning on or after January 1, 2023. For tax years beginning after December 31, 2021, the Tax Cuts & Jobs Act of 2017 eliminated the option to deduct research and development expenditures as incurred and instead required taxpayers to capitalize and amortize them over five or 15 years beginning in 2022. Since the Company is in a net operating loss position, the capitalization of research and development costs did not have a material impact on the Company's results of operations for the year ended December 31, 2023. The Company will continue to monitor the possible future impact of changes in tax legislation.

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, 2023 and 2022, the Company had $1.0 million and $0.7 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 September 4, 2023 the Company's Australian subsidiary received a $0.6 million tax refund from the Australian Taxation Office related to the 2022 tax year.

Note 14 – Contingencies

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. Lingmed filed an answer to Cend's response on July 11, 2022. At a Case Management Conference held on August 4, 2023, the Court set a trial date in the matter for August 2, 2024. The Company denies these allegations made by Lingmed and intends to vigorously defend itself.

Note 15 – Technology Transfer Agreement

Impilo Therapeutics

In July 2023, the Company entered into a technology transfer agreement with Impilo Therapeutics, Inc. ("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 (Note 16), Impilo cancelled the original stock certificate for 766,000 shares and reissued 574,500 shares of its pre-seed preferred stock to the Company.

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 LSTA1. 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, Cend issued a total of 382,030 shares of common stock, as adjusted for the Reverse Stock Split and Exchange Ratio. The Company is required to pay an annual license maintenance fee of $10,000 increasing to $20,000 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, which, pursuant to the technology transfer agreement with Impilo, resulted in SBP receiving 191,500 apportioned 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.

In October 2021, Cend entered into a license agreement with SBP under which Cend was granted an exclusive, royalty-bearing license to certain patent rights and know-how controlled by SBP. The agreement provides Cend with the rights to grant and authorize sublicenses to use, sell, and otherwise exploit the patent rights. The Company is required to pay an annual license maintenance fee of $20,000, increasing to $30,000 on year four of the agreement. Further, the Company could be required to make milestone payments to SBP upon completion of certain regulatory and commercial milestones. The aggregate potential milestone payments are approximately $23.2 million. The Company is obligated 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 varying sublicense fees, ranging from 10% to 25%, dependent on when the related milestones are reached. On September 14, 2023, pursuant to the technology transfer agreement with Impilo, the license was assigned in full to Impilo.

SBP did not own shares of the Company's common stock as of December 31, 2023.

University of California at San Diego

In March 2021, Cend entered into a license agreement with the University of California at San Diego ("UCSD") under which Cend was granted an exclusive, royalty-bearing license to certain patent rights related to the development of nano-particles to modulate immune response. The agreement provides the Company with the rights to grant and authorize sublicenses to use, sell and otherwise exploit the patent rights. The Company could be required to make milestone payments to UCSD upon completion of certain regulatory and commercial milestones. The aggregate potential milestone payments are approximately $1.2 million. The Company has also agreed to pay UCSD royalties of 1.5% of net sales of products sold by the Company or through a sublicense, subject to certain reductions. Additionally, the Company agreed to pay UCSD varying sublicense fees, ranging from 10% to 20%, dependent on when the related milestones are reached.

The agreement will expire upon the expiration of the longest-lived patent rights. The agreement may be terminated in its entirety by the Company at any time by giving UCSD ninety days' prior written notice. The agreement may be terminated in its entirety by UCSD if the Company, at any time, (i) fails to perform or violates any term of the agreement and fails to cure the default within sixty days. Upon termination of the agreement for any reason, UCSD may terminate a sublicensee but will allow the Company to assign any sublicenses to UCSD provided a) that the sublicensee is in good standing upon termination of the agreement with the Company; and b) the sublicensee is not currently involved in litigation as an adverse party to UCSD.

On August 2, 2023, pursuant to the technology transfer agreement with Impilo, the license was assigned in full to Impilo.

Massachusetts Institute of Technology

In October 2021, Cend entered into a license agreement with the Massachusetts Institute of Technology ("MIT") under which Cend was granted an exclusive, royalty-bearing license to certain patent rights related to the development of tissue specific delivery of interfering RNA. 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, Cend issued a total of 43,236 shares of common stock, as adjusted for the Reverse Stock Split and Exchange Ratio. The Company is required to pay an annual license maintenance fee of $20,000, increasing to $25,000 for year two and three of the agreement, increasing to $50,000 on year four of the agreement and thereafter until the first commercial sale, and increasing to $150,000 each year of the agreement after the first commercial sale. Further, the Company could be required to make milestone payments to MIT upon completion of certain regulatory and commercial milestones. The aggregate potential milestone payments are approximately $5.0 million. The Company has also agreed to pay MIT royalties of 2% of net sales of products sold by the Company or through a sublicense, subject to certain reductions. Additionally, the Company is obligated to pay MIT varying sublicense fees, ranging from 3% to 20%, depending on when the related milestones are reached. In connection with the close of the Merger, the Company was required to pay MIT a change of control fee of $0.3 million.

The agreement expires upon the expiration or abandonment of all valid claims. The agreement may be earlier terminated in its entirety by the Company at any time by giving MIT six months prior written notice. The agreement may also be terminated in its entirety by MIT if the Company, at any time, (i) defaults in the payment of any sum when due and fails to make such payment within thirty days after receipt of written notice, or (ii) commits a material breach of its obligations under the agreement (aside from item (i)) and fails to cure that breach within sixty days after receipt of written notice. Upon termination of the agreement for any reason, the rights and licenses granted to the Company shall terminate and revert to MIT. Upon termination of the agreement for any reason, MIT may terminate a sublicensee but will allow the Company to assign any sublicenses to MIT provided that the sublicensee is in good standing upon termination of the agreement with the Company.

On June 30, 2023, in accordance with the provisions of the license agreement, the Company provided notice to MIT that the license agreement would terminate effective December 30, 2023.

MIT owned 43,236 shares of the Company's common stock as of December 31, 2023.

Note 17 – Research Collaboration and License Agreement

Exclusive License and Collaboration Agreement

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 LSTA1 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 LSTA1 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 Merger. In addition, Cend received and recognized as revenue a $5.0 million development milestone prior to the Merger. The Company is eligible to receive additional developmental 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%.

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.

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 the Chief Executive Officer/ Principal Financial Officer, 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, 2023, we evaluated, with the participation of our management, including our Chief Executive Officer (who serves as both Principal Executive Officer and Principal Financial Officer), 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 Chief Executive Officer 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 Chief Executive Officer, 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, 2023. 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, 2023, 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, 2023 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, 2023, 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 Matters," and "Code of Ethics" in our Proxy Statement for the 2024 Annual Meeting of Stockholders.

The following table sets forth the name and position of each of our executive officers and directors as of February 29, 2024.

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
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

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 Æterna 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 where she served as a Global Safety Physician and Global Study Physician. Her experience ranges over multiple therapeutic indications including cardiovascular/metabolic, rare diseases, gastrointestinal, neuroscience, oncology, immunology, and women's health.

Dr. Buck currently serves as a Senior Medical Advisor and member of the Scientific Advisory Board for global contract research organization; Biorasi Inc.

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.

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.

In addition, he has served on the board of directors of Recipharm, a leading pharmaceutical contract development & manufacturing organization since March 2021 and Golden Arrow Merger Corp. since March 2021. In addition, since 2021 he has served on the board of directors of Formulated Solutions, a topicals CDMO where he is the chairman of the board; BioIVT, a leading supplier of biologics specimens for biotech research; BIOVECTRA, a leading small molecule and biologics CDMO; and NJ Bio, a leading antibody drug conjugate contract research organization.

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 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, since January 2003. 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 2024 Annual Meeting of Stockholders. The section entitled "Pay Versus Performance" in our 2024 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 2024 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 "Management and Corporate Governance Matters" in our Proxy Statement for the 2024 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 2024 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 70 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
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 and June 14, 2023.
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 and June 14, 2023.
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	+	Severance Agreement with David Slack, dated May 1, 2023 (filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, filed with the SEC on August 14, 2023).
10.9		Form of Purchase Agreement, dated April 23, 2020, by and between Caladrius Biosciences, Inc. and each purchaser identified on the signature pages thereto (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on April 24, 2020).
10.10		Placement Agent Agreement, dated November 5, 2019, as subsequently amended on each of March 11, 2020, April 23, 2020 and May 25, 2020, by and between Caladrius Biosciences, Inc. and H.C. Wainwright & Co., LLC (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on May 26, 2020).
10.11		Form of Purchase Agreement, dated May 25, 2020, by and between Caladrius Biosciences, Inc. and each purchaser identified on the signature pages thereto (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on May 26, 2020).
10.12		Form of Purchase Agreement, dated July 10, 2020, by and between Caladrius Biosciences, Inc. and each purchaser identified on the signature pages thereto (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on July 10, 2020).
10.13		Form of Registration Rights Agreement, dated July 10, 2020, by and between Caladrius Biosciences, Inc. and each purchaser identified on the signature pages thereto (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on July 10, 2020).
10.14		Form of Purchase Agreement, dated January 21, 2021, by and between Caladrius Biosciences, Inc. and certain Investors, as defined therein (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on January 25, 2021).
10.15		Form of Registration Rights Agreement, dated January 21, 2021, by and between Caladrius Biosciences, Inc. and each purchaser identified on the signature pages thereto (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on January 25, 2021).
10.16		Form of Institutional Securities Purchase Agreement, by and between Caladrius Biosciences, Inc. and each purchaser identified on the signature pages thereto (incorporated by reference to Exhibit 10.1 of the Registrant’s Form 8-K filed on February 16, 2021).
10.17		Form of Institutional Additional Securities Purchase Agreement, by and between Caladrius Biosciences, Inc. and each purchaser identified on the signature pages thereto (incorporated by reference to Exhibit 10.2 of the Registrant’s Form 8-K filed on February 16, 2021).
10.18		Placement Agent Agreement, dated February 11, 2021, by and between Caladrius Biosciences, Inc. and H.C. Wainwright & Co., LLC (filed as Exhibit 10.3 to the Company's Current Report on Form 8-K, filed with the SEC on February 16, 2021).
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.
97		Incentive Recoupment Policy, effective as of March 28, 2023.
21.1		Subsidiaries of Lisata Therapeutics, Inc.
23.1		Consent of Grant Thornton LLP.

31.1		Certification of Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32	†	Certification of Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant Section 302 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

+ 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.

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 February 29, 2024.

LISATA THERAPEUTICS, INC.

By: /s/ David J. Mazzo, PhD

Name: David J. Mazzo
Title: Chief Executive Officer
(Principal Executive Officer, Principal Financial Officer and Principal Accounting 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
/s/ David J. Mazzo David J. Mazzo, PhD	Director and Chief Executive Officer (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)	February 29, 2024
/s/ Gregory B. Brown Gregory B. Brown, MD	Chairman of the Board of Directors	February 29, 2024
/s/ Mohammad Azab Mohamad Azab, MD, MBA	Director	February 29, 2024
/s/ Cynthia L. Flowers Cynthia L. Flowers, MBA	Director	February 29, 2024
/s/ Heidi Henson Heidi Henson	Director	February 29, 2024
/s/ Steven M. Klosk Steven M. Klosk, JD	Director	February 29, 2024