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

FORM 10-K

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

For the Fiscal Year Ended December 31, 2022
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 000-22245

SEELOS THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Nevada	**87-0449967**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

300 Park Avenue, 2nd Floor, New York, NY 10022
(Address of principal executive offices and zip code)

(646) 293-2100
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, par value $0.001 per share	**SEEL**	**The Nasdaq Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act: None.

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in 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 Act). Yes ☐ No ☒

As of February 24, 2023, 108,110,790 shares of the common stock, par value $0.001, of the registrant were outstanding.

The aggregate market value of the voting stock held by non-affiliates of the registrant the last business day of the registrant's most recently completed second fiscal quarter: $69.9 million based upon the closing sale price of the registrant's common stock of $0.68 on that date. Shares of the registrant's common stock held by each officer and director and by each person known to own in excess of 10% of outstanding shares of the registrant's common stock have been excluded in that such persons may be deemed to be affiliates. The determination of affiliate status is not necessarily a conclusive determination for other purposes.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required to be disclosed in Part III of this report is incorporated by reference from the information contained in the registrant's Definitive Proxy Statement for the 2023 Annual Meeting of Stockholders, which Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year ended December 31, 2022.

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PART I.

Cautionary Note Regarding Forward-Looking Statements

This report includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Those statements include statements regarding the intent, belief or current expectations of Seelos Therapeutics, Inc. and its subsidiaries ("we," "us," "our," the "Company" or "Seelos") and our management team. Any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and actual results may differ materially from those projected in the forward-looking statements. These risks and uncertainties include but are not limited to those risks and uncertainties set forth in Item 1A of this Report. In light of the significant risks and uncertainties inherent in the forward-looking statements included in this Report, the inclusion of such statements should not be regarded as a representation by us or any other person that our objectives and plans will be achieved. Further, these forward-looking statements reflect our view only as of the date of this report. Except as required by law, we undertake no obligations to update any forward-looking statements and we disclaim any intent to update forward-looking statements after the date of this report to reflect subsequent developments. Accordingly, you should also carefully consider the factors set forth in other reports or documents that we file from time to time with the Securities and Exchange Commission ("SEC").

We have common law trademark rights in the unregistered marks "Seelos Therapeutics, Inc.," "Seelos" and the Seelos logo in certain jurisdictions. Vitaros is a registered trademark of Ferring International Center S.A. ("Ferring") in certain countries outside of the United States. This Annual Report on Form 10-K also includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this Annual Report on Form 10-K appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trademarks and tradenames.

ITEM 1. BUSINESS

We are a clinical-stage biopharmaceutical company focused on achieving efficient development of products that address significant unmet needs in Central Nervous System ("CNS") disorders and other rare disorders.

Our business model is to advance multiple late-stage therapeutic candidates with proven mechanisms of action that address large markets with unmet medical needs and for which there is a strong economic and scientific rationale for development.

Our product development pipeline is as follows:

Product	Indication	Development Phase	Development Status
SLS-002 Intranasal Racemic Ketamine	Acute Suicidal Ideation and Behavior (ASIB) in Major Depressive Disorder (MDD)	Phase II	Completed open-label patient enrollment and announced the initial topline data from Part 1 of the proof-of-concept study on May 17, 2021; enrollment of Part 2 of a registration directed study ongoing; data readout for Part 2 expected in the third quarter of 2023
SLS-005 IV Trehalose	Amyotrophic Lateral Sclerosis (ALS)	Phase II/III	Completed enrollment of final participants in February 2023 in the registrational study; data readout expected in late 2023
	Spinocerebellar Ataxia (SCA)	Phase IIb/III	In October 2022, we announced dosing of the first participant in the registrational study; enrollment ongoing
	Huntington's Disease (HD) and Alzheimer's Disease (AD)	Phase II	Obtaining biomarker activity
SLS-004 Gene Therapy	Parkinson's Disease (PD)	Pre-IND	Preclinical *in vivo* studies ongoing; in December 2022, we announced partial results from a study demonstrating downregulation of α-synuclein
SLS-007 Peptide Inhibitor	Parkinson's Disease (PD)	Pre-IND	Preclinical study completed and analysis of the results ongoing; next steps for development of this program will be decided in concert with SLS-004 results and readouts, as both target the same pathway upstream

Lead Programs

Our lead programs are currently SLS-002 for the potential treatment of Acute Suicidal Ideation and Behavior ("ASIB") in patients with Major Depressive Disorder ("MDD") and SLS-005 for the potential treatment of Amyotrophic Lateral Sclerosis ("ALS") and Spinocerebellar Ataxia ("SCA"). SLS-005 for the potential treatment of Sanfilippo Syndrome currently requires additional natural history data, which is being considered.

SLS-002 is intranasal racemic ketamine with two investigational new drug applications ("INDs"). The lead program is focused on the treatment of ASIB in MDD. SLS-002 was originally derived from a Javelin Pharmaceuticals, Inc./Hospira, Inc. program with 16 clinical studies involving approximately 500 subjects. SLS-002 is being developed to address an unmet need for an efficacious drug to treat suicidality in the United States. Traditionally, anti-depressants have been used in this setting but many of the existing treatments are known to contribute to an increased risk of suicidal thoughts in some circumstances, and if and when they are effective, it often takes weeks for the full therapeutic effect to be manifested. We believe there is a large opportunity in the United States and European markets for products in this space. Based on information gathered from the databases of the Agency for Healthcare Research and Quality, there were approximately 1.48 million visits to emergency rooms for suicidal ideation or suicide attempts in 2017 in the United States alone. Experimental studies suggest ketamine has the potential to be a rapid, effective treatment for depression and suicidality.

The clinical development program for SLS-002 includes two parallel healthy volunteer studies (Phase I). We announced interim data from our Phase I study of SLS-002 during the quarterly period ended March 31, 2020. As a result, in March 2020, we completed a Type C meeting with the U.S. Food and Drug Administration ("FDA") and received guidance to conduct a Phase II proof of concept ("PoC") study of SLS-002 for ASIB in patients with MDD, to support the further clinical development of this product candidate, together with nonclinical data under development.

As a result of the Type C meeting and the Fast Track designation for SLS-002 for the treatment of ASIB in patients with MDD, we believe we are well positioned to pursue the FDA's expedited programs for drug development and review.

On June 23, 2020, we announced the final safety data from our Phase I pharmacokinetics/pharmacodynamics study of intranasal racemic ketamine (SLS-002) as well as the planned design of a Phase II double blind, placebo-controlled PoC study for ASIB in subjects with MDD. We initiated this PoC study in two parts: Part 1 was an open-label study of 17 subjects, and is being followed by Part 2, which is a double blind, placebo-controlled study of approximately 175 subjects. On January 15, 2021, we announced dosing of the first subjects in Part 1 of the PoC study. On March 5, 2021, we announced the completion of open-label enrollment of subjects in Part 1 of the PoC study. On May 17, 2021, we announced positive topline data from Part 1 of the POC study, the open-label cohort, of our study of SLS-002 (intranasal racemic ketamine), demonstrating a significant treatment effect and a well-tolerated safety profile for ASIB in patients with MDD. This study enrolled 17 subjects diagnosed with MDD requiring psychiatric hospitalization due to significant risk of suicide with a baseline score of ≥ 28 points on the Montgomery-Åsberg Depression Rating Scale ("MADRS"), a score of 5 or 6 on MADRS Item-10, a score of ≥ 15 points on the Sheehan-Suicidality Tracking Scale (S-STS) total score and a history of previous suicide attempt(s), as confirmed on the Columbia Suicide Severity Rating Scale (C-SSRS) with a history of at least one actual attempt, or if the attempt was interrupted or aborted, is judged to have been serious in intent. SLS-002 demonstrated a 76.5% response rate (response meaning 50% reduction from baseline) in the primary endpoint on MADRS twenty-four hours after first dose, with a mean reduction in total score from 39.4 to 14.5 points.

On July 6, 2021, we announced dosing of the first subject in Part 2 of the planned registration directed study. Based on feedback from a Type C meeting with the FDA in June 2021, we increased the subjects in Part 2 to increase the sample size and power to support a potential marketing application.

SLS-005 is IV trehalose, a protein stabilizer that crosses the blood-brain-barrier and activates autophagy and the lysosomal pathway. Based on preclinical and *in vitro* studies, there is a sound scientific rationale for developing trehalose for the treatment of ALS, SCA and other indications such as Sanfilippo Syndrome. Trehalose is a low molecular weight disaccharide (0.342 kDa) that protects against pathological processes in cells. It has been shown to penetrate muscle and cross the blood-brain-barrier. In animal models of several diseases associated with abnormal cellular protein aggregation, it has been shown to reduce pathological aggregation of misfolded proteins as well as to activate autophagy pathways through the activation of Transcription Factor EB ("TFEB"), a key factor in lysosomal and autophagy gene expression. Activation of TFEB is an emerging therapeutic target for a number of diseases with pathologic accumulation of storage material.

Trehalose 90.5 mg/mL IV solution has demonstrated promising clinical potential in prior Phase II clinical development for oculopharyngeal muscular dystrophy ("OPMD") and spinocerebellar ataxia type 3 ("SCA3"), also known as Machado Joseph disease, with no significant safety signals to date and encouraging efficacy results. Pathological accumulation of protein aggregates within cells, whether in the CNS or in muscle, eventually leads to loss of function and ultimately cell death. Prior preclinical studies indicate that this platform has the potential to prevent mutant protein aggregation in other devastating PolyA/PolyQ diseases.

We own three United States patents for parenteral administration of trehalose for patients with OPMD and SCA3, all of which are expected to expire in 2034. In addition, Orphan Drug Designation ("ODD") for OPMD and SCA3 has been secured in the United States and in the European Union ("EU"). In February 2019, we assumed a collaborative agreement, turned subsequently into a research grant, with Team Sanfilippo Foundation ("TSF"), a nonprofit medical research foundation founded by parents of children with Sanfilippo Syndrome. On April 30, 2020, we were granted ODD for SLS-005 in Sanfilippo Syndrome from the FDA. SLS-005 was previously granted ODD from the FDA and European Medicines Agency for SCA3 and OPMD as well as Fast Track designation for OPMD. On August 25, 2020, we were issued U.S. patent number 10,751,353 titled "COMPOSITIONS AND METHODS FOR TREATING AN AGGREGATION DISEASE OR DISORDER" which relates to trehalose (SLS-005). The issued patent covers the method of use for trehalose (SLS-005) formulation for treating a disease or disorder selected from any one of the following: spinal and bulbar muscular atrophy, dentatombral-pallidoluysian atrophy, Pick's disease, corticobasal degeneration, progressive supranuclear palsy, frontotemporal dementia or parkinsonism linked to chromosome 17. On May 15, 2020, we were granted Rare Pediatric Disease Designation ("RPDD") for SLS-005 in Sanfilippo Syndrome from the FDA. RPDD is an incentive program created under the Federal Food, Drug, and Cosmetic Act to encourage the development of new therapies for the prevention and treatment of certain rare pediatric diseases. On May 27, 2021, we announced that we were granted ODD for SLS-005 in ALS from the European Medicines Agency. In December 2020, we announced the selection of SLS-005 for the Healey ALS platform trial led by Harvard Medical School, Massachusetts. The Healey ALS platform trial is designed to study multiple potential treatments for ALS simultaneously. The platform trial model aims to greatly accelerate the study access, reduce costs and shorten development timelines. On February 28, 2022, we announced the dosing of the first participants in the Healey ALS platform trial. In November 2021, we announced the FDA acceptance of an IND and grant of Fast Track designation for SLS-005 for the treatment of SCA. In July 2022, we announced dosing of the first patient in an open-label basket study in Australia for the treatment of patients with ALS, SCA, and Huntington's disease ("HD"). In October 2022, we also announced the dosing of the first participant in the registrational Phase II/III study for the treatment of SCA.

Additionally, we are developing several preclinical programs, most of which have well-defined mechanisms of action, including SLS-004, licensed from Duke University, and SLS-007, licensed from The Regents of the University of California, for the potential treatment of Parkinson's Disease ("PD").

Strategy and Ongoing Programs

SLS-002: The clinical development program for SLS-002 includes two parallel healthy volunteer studies (Phase I). Following these Phase I studies, we completed a Type C meeting with the FDA in March 2020 and received guidance to conduct a Phase II PoC study of SLS-002 for ASIB in subjects with MDD. We released topline data for Part 1 of our open-label study on May 17, 2021. We initiated enrollment in Part 2 of the registration directed study on July 6, 2021, and we anticipate enrollment completing in mid-2023, with a data readout for Part 2 expected in the third quarter of 2023.

SLS-005: We completed enrollment in February 2023 for a clinical study in ALS and began enrollment for a clinical study in SCA in October 2022. In December 2020, we announced the selection of SLS-005 for the Healey ALS platform trial led by Harvard Medical School, Massachusetts. The Healey ALS platform trial is designed to study multiple potential treatments for ALS simultaneously. The platform trial model aims to greatly accelerate the study access, reduce costs, and shorten development timelines. On February 28, 2022, we announced dosing of the first participants in the Healey ALS platform trial. In November 2021, we announced the FDA acceptance of an IND and grant of Fast Track designation for SLS-005 for the treatment of SCA. In July 2022, we announced dosing of the first patient in an open-label basket study in Australia for the treatment of patients with ALS, SCA, and HD. In October 2022, we also announced the dosing of the first participant in the registrational Phase II/III study for the treatment of SCA. During 2022, we received regulatory approval in Australia to commence a study pursuing collection of certain biomarker data in Alzheimer's Disease. We are continuing to consider trials in Sanfilippo Syndrome and are seeking more natural history data based on the guidance from regulatory agencies. In February 2023, we announced the completion of enrollment of the study and data readout is expected in late 2023.

SLS-004 is an all-in-one lentiviral vector, targeted for gene editing through DNA methylation within intron 1 of the synuclein alpha ("SNCA") gene that expresses alpha-synuclein protein. SLS-004, when delivered to dopaminergic neurons derived from human induced pluripotent stem cells of a PD patient, modified the expression on alpha-synuclein ("α-synuclein") and exhibited reversal of the disease-related cellular-phenotype characteristics of the neurons. The role of mutated SNCA in PD pathogenesis and the need to maintain the normal physiological levels of α-synuclein protein emphasize the yet unmet need to develop new therapeutic strategies, such as SLS-004, targeting the regulatory mechanism of α-synuclein expression. On May 28, 2020, we announced the initiation of a preclinical study of SLS-004 in PD through an all-in-one lentiviral vector targeting the SNCA gene. We are constructing a bimodular viral system harboring an endogenous α-synuclein transgene and inducible regulated repressive CRISPR/dCas9-unit to achieve suppression of PD-related pathologies. On July 7, 2021, we announced positive *in vivo* data demonstrating down-regulation of SNCA mRNA and protein expression under this study. In December 2022, we announced *in vivo* data demonstrating that a single dose of SLS-004 was successful in reversing some of the key hallmarks of PD in a humanized mouse model. These findings observed in an *in vivo* humanized PD model validate and extend prior findings from *in vitro* data using SLS-004. SLS-004 demonstrated therapeutically desirable change in SNCA expression that led to reversing the key hallmarks of PD in the model towards normal physiological levels, indicating disease modifying effect of single dose administration of SLS-004, a CRISPR/dCas-9 based gene therapy for PD.

SLS-007 is a rationally designed peptide-based approach, targeting the nonamyloid component core ("NACore") of α-synuclein to inhibit the protein from aggregation. Recent *in vitro* and cell culture research has shown that SLS-007 has the ability to stop the propagation and seeding of α- synuclein aggregates. We will evaluate the potential for *in vivo* delivery of SLS-007 in a PD transgenic mice model. The goal will be to establish *in vivo* pharmacokinetics/pharmacodynamics and target engagement parameters of SLS-007, a family of anti- α -synuclein peptidic inhibitors. On June 25, 2020, we announced the initiation of a preclinical study of SLS-007 in PD delivered through an adeno associated viral ("AAV") vector targeting the non-amyloid component core of α-synuclein. We have initiated an *in vivo* preclinical study of SLS-007 in rodents to assess the ability of two specific novel peptides, S62 and S71, delivered via AAV1/2 viral vector, to protect dopaminergic function in the AAV A53T overexpression mice model of PD. Production of AAV1/2 vectors encoding each of the two novel peptides incorporating hemagglutinin tags has already been completed. The results are currently being analyzed and the next steps for development of this program will be decided in concert with SLS-004 results and readouts, as both target the same pathway upstream.

We intend to become a leading biopharmaceutical company focused on neurological and psychiatric disorders, including orphan indications. Our business strategy includes:

- advancing SLS-002 in ASIB in MDD and post-traumatic stress disorder;
- advancing SLS-004 in PD;
- advancing SLS-005 in ALS, SCA, HD and Sanfilippo Syndrome;
- advancing new formulations of SLS-005 in neurological diseases; and
- acquiring synergistic assets in the CNS therapy space through licensing and partnerships.

We also have two legacy product candidates: a product candidate in the United States for the treatment of erectile dysfunction, which we in-licensed from Warner Chilcott Company, Inc., now a subsidiary of Allergan plc; and a product candidate which has completed a Phase IIa clinical trial for the treatment of Raynaud's Phenomenon, secondary to scleroderma, for which we own worldwide rights.

Impact of COVID-19

Beginning in the fourth quarter of 2021 and through the fourth quarter of 2022, we experienced a slowdown in patient enrollment primarily due to staffing issues at our study sites related to the spike in COVID-19 cases due to the Omicron variant and its sub-variants. Recently, we have seen staffing issues improving, but we cannot be certain that this trend will continue as additional variants emerge and COVID-19 continues to circulate and spread. However, the pandemic has not materially affected our liquidity as we maintain our resources in the form of cash.

In addition, although preventative measures taken to date did not have a material adverse impact on our business during 2022, the continued impact of the COVID-19 pandemic on our business, financial condition and results of operations is unknown and will depend on future developments and risks, which are highly uncertain and cannot be predicted. These developments and risks include, among others, the duration and severity of the COVID-19 pandemic, the emergence or spread of new COVID-19 variants, the impact on the capital markets, the impact on our partners and the regulatory agencies that oversee our sector and any additional preventative and protective actions that governmental authorities, or we, may implement, any of which may result in an extended period of business disruption, including potential delays in commencing future clinical trials, or in completing enrollment for any clinical trials we may commence or in the U.S. Food and Drug Administration ("FDA") or other regulatory agencies conducting in-person inspections or accommodations for alternatives to in-person inspections. Any resulting financial impact cannot be reasonably estimated at this time, but the COVID-19 pandemic may force us to make adjustments to our business, our plans and our timeline for developing assets, including our programs. In addition, the pandemic is currently not anticipated to have a material adverse impact on our business, financial condition and results of operations, including our ability to raise additional capital. See Part I, Item 1A, Risk Factors, for an additional discussion of risks related to COVID-19.

Merger

On January 24, 2019, our company (which was formerly named "Apricus Biosciences, Inc.") completed a business combination with Seelos Therapeutics, Inc., a Delaware corporation ("STI"), in accordance with the terms of the Agreement and Plan of Merger and Reorganization (the "Merger Agreement") entered into on July 30, 2018. Pursuant to the Merger Agreement, (i) a former subsidiary of ours merged with and into STI, with STI (renamed "Seelos Corporation") continuing as a wholly-owned subsidiary of ours and the surviving corporation of the merger and (ii) our company was renamed "Seelos Therapeutics, Inc." (the "Merger").

Acquisition of Assets from Bioblast Pharma Ltd. ("Bioblast")

On February 15, 2019, we entered into an Asset Purchase Agreement (the "Bioblast Asset Purchase Agreement") with Bioblast. Pursuant to the Bioblast Asset Purchase Agreement, we acquired all of the assets of Bioblast relating to a therapeutic platform known as Trehalose (the "Bioblast Asset Purchase"). At the closing of the Bioblast Asset Purchase (the "Bioblast Closing"), we paid to Bioblast $1.5 million in cash in February 2019 and an additional $2.0 million in cash in February 2020. Accordingly, we recognized a $3.5 million charge to research and development expense during the three months ended March 31, 2019. Under the terms of the Bioblast Asset Purchase Agreement, we agreed to pay additional consideration to Bioblast upon the achievement of certain milestones in the future, as follows: (1) within 15 days following the completion of our or our affiliate's first Phase II(b) clinical trial of Trehalose satisfying certain criteria, we will pay to Bioblast $8.5 million in cash; and (2) within 15 days following the approval for commercialization by the FDA or the Health Products and Food Branch of Health Canada of the first new drug application (an "NDA") or New Drug Submission, respectively, of Trehalose filed by us or our affiliates, we will pay to Bioblast $8.5 million in cash. In addition, we agreed to pay Bioblast a cash royalty equal to 1% of the net sales of Trehalose. Under the terms of the Bioblast Asset Purchase, we assumed a collaborative agreement with TSF. On July 15, 2019, we amended the agreement whereby we agreed to assume responsibility for a Phase II(b)/III clinical trial and TSF agreed to provide a grant of up to $1.5 million towards the funding of the trial.

Acquisition of License from Stuart Weg, MD

On August 29, 2019, we entered into an amended and restated exclusive license agreement with Stuart Weg, M.D. (the "Weg License Agreement"), pursuant to which we were granted an exclusive worldwide license to certain intellectual property and regulatory materials related to SLS-002. Under the terms of the Weg License Agreement, we paid an upfront license fee of $75,000 upon execution of the agreement. We agreed to pay additional consideration to Dr. Weg as follows: (i) $0.1 million on January 2, 2020, (ii) $0.125 million on January 2, 2021, and (iii) in the event the FDA has not approved an NDA for a product containing ketamine in any dosage on or before December 31, 2021, $0.2 million on January 2, 2022. We paid the required $0.1 million on January 2, 2020, $0.125 million on January 2, 2021, and $0.2 million on January 3, 2022. As further consideration, we agreed to pay Dr. Weg certain milestone payments consisting of (i) $0.1 million and shares of common stock equal to $0.15 million divided by the closing sales price of our common stock upon the issuance of the first patent directed to an anxiety indication, (ii) $0.5 million after the locking of the database and unblinding the data for the statistically significant readout of a Phase III trial of an intranasal racemic ketamine product that has been conducted for the submission under an NDA or equivalent seeking regulatory approval in the United States, the United Kingdom, France, Germany, Italy, Spain, China or Japan, or seeking regulatory from the EMA in the EU, for such product (the "Milestone Product"), (iii) $3.0 million upon FDA approval of an NDA for the Milestone Product, (iv) $2.0 million upon regulatory approval by the EMA for the Milestone Product, and (v) $1.5 million upon regulatory approval in Japan for the Milestone Product; provided, however, that the maximum amount to be paid by us under milestones (i)-(v) will be $6.6 million. We will also pay to Dr. Weg a royalty percentage equal to 2.25% on the sale of each product containing ketamine in any dosage.

Acquisition of License from The Regents of the University of California

On March 7, 2019, we entered into an exclusive license agreement (the "UC Regents License Agreement") with The Regents of the University of California ("The UC Regents") pursuant to which we were granted an exclusive license to intellectual property owned by The UC Regents pertaining to a technology that was created by researchers at the University of California, Los Angeles (UCLA). Such technology relates to a family of rationally-designed peptide inhibitors that target the aggregation of α-synuclein. We plan to study this initial approach in PD and will further evaluate the potential clinical approach in other disorders affecting the CNS. This program is now known as SLS-007. Upon entry into the UC Regents License Agreement, we paid to The UC Regents $0.1 million. Under the terms of the UC Regents License Agreement, we agreed to pay additional consideration upon the achievement of certain milestones in the future, as follows: (i) within 90 days following dosing of the first patient in a Phase I clinical trial, we will pay $50,000; (ii) within 90 days following dosing of the first patient in a Phase II clinical trial, we will pay $0.1 million; (iii) within 90 days following dosing of the first patient in a Phase III clinical trial, we will pay $0.3 million; (iv) within 90 days following the first commercial sales in the U.S., we will pay $1.0 million; (v) within 90 days following the first commercial sales in any European market, we will pay $1.0 million; and (vi) within 90 days following $250 million in cumulative worldwide net sales of a licensed product, we will pay $2.5 million. We are also obligated to pay a single digit royalty on sales of the product, if any. In addition, if we fail to achieve certain milestones within a specified timeframe, The UC Regents may terminate the agreement or reduce our license to a nonexclusive license.

Acquisition of License from Duke University

On June 27, 2019, we entered into an exclusive license agreement (the "Duke License Agreement") with Duke University pursuant to which we were granted an exclusive license to a gene therapy program targeting the regulation of the SNCA gene, which encodes α-synuclein expression. We plan to study this initial approach in PD and will further evaluate the potential clinical approach in other disorders affecting the CNS. This program is now known as SLS-004. Upon entry into the Duke License Agreement, we paid to Duke University $0.1 million. We agreed to pay additional consideration to Duke University upon the achievement of certain milestones in the future, as follows: (i) within 30 days following filing of an IND following the completion of preclinical studies including comprehensive validation of the platform, we will pay $0.1 million; (ii) within 30 days following dosing of the first patient in a Phase I clinical trial, we will pay $0.2 million; (iii) within 30 days following dosing of the first patient in a Phase II clinical trial, we will pay $0.5 million; (iv) within 30 days following dosing of the first patient in a Phase III clinical trial, we will pay $1.0 million; and (v) within 30 days following an NDA approval, we will pay $2.0 million. We are also obligated to pay a single digit royalty on sales of the product, if any. In addition, if we fail to achieve certain milestones within a specified timeframe, Duke University may terminate the agreement.

Acquisition of License from Ligand Pharmaceuticals Incorporated

On September 21, 2016, we entered into a License Agreement (the "License Agreement") with Ligand Pharmaceuticals Incorporated ("Ligand"), Neurogen Corporation and CyDex Pharmaceuticals, Inc. (collectively, the "Licensors"), pursuant to which, among other things, the Licensors granted us an exclusive, perpetual, irrevocable, worldwide, royalty-bearing, nontransferable right and license under (i) patents related to a product known as Aplindore, which is now known as SLS-006, acetaminophen (as it may have been or may be modified for use in a product to be administered by any method in any form including, without limitation injection and intravenously, the sole active pharmaceutical ingredient of which is acetaminophen), which is now known as SLS-012, an H3 receptor antagonist, which is now known as SLS-010, and either or both of the Licensors' two proprietary CRTh2 antagonists, which are now known collectively as SLS-008 (collectively, the "Licensed Products"), and (ii) copyrights, trade secrets, moral rights and all other intellectual and proprietary rights related thereto. We are obligated to use commercially reasonable efforts to (a) develop the Licensed Products, (b) obtain regulatory approval for the Licensed Products in the United States or a Major Market, and (c) commercialize the Licensed Products in each country where regulatory approval is obtained. We have the exclusive right and sole responsibility and decision-making authority to research and develop any Licensed Products and to conduct all clinical trials and non-clinical studies we believe appropriate to obtain regulatory approvals for commercialization of the Licensed Products. We also have the exclusive right and sole responsibility and decision-making authority to commercialize any of the Licensed Products.

As partial consideration for the grant of the rights and licenses under the License Agreement, we paid to Ligand a nominal option fee. As further partial consideration for the grant of the rights and licenses to us under the License Agreement, we were obligated to pay to Ligand an aggregate of $1.3 million within 30 days after the closing of the issuance and sale by us of debt and/or equity securities for gross proceeds to us of at least $7.5 million. In connection with the closing of the Merger, we issued 392,307 shares of common stock to settle this obligation. As further partial consideration for the grant of the rights and licenses to us by Ligand under the License Agreement, we agreed to pay to Ligand certain one-time, non-refundable milestone payments upon the achievement of certain financing milestones, consisting of (i) the lesser of $3.5 million or 10% of the net proceeds to us in the event of our initial public offering or a financing transaction consummated in connection with a transaction as a result of which our business becomes owned or controlled by an existing issuer with a class of securities registered under the Exchange Act and immediately after such transaction, our security holders as of immediately before such transaction own, as a result of such transaction, at least 35% of the equity securities or voting power of such issuer, or (ii) the lesser of $3.5 million or 10% of the net proceeds to us in the event we are acquired. In connection with the closing of the Merger, we issued 408,946 shares of common stock to settle this obligation.

As further partial consideration for the grant of the rights and licenses under the License Agreement, we agreed to pay Ligand certain one-time, non-refundable regulatory milestone payments in connection with the Licensed Products, other than in connection with Aplindore for the indication of PD or Restless Leg Syndrome, consisting of (i) $750,000 upon submission of an application with the FDA or equivalent foreign body for a particular Licensed Product, (ii) $3.0 million upon FDA approval of an application for a particular Licensed Product, (iii) $1.125 million upon regulatory approval in a Major Market for a particular Licensed Product, and (iv) $1.125 million upon regulatory approval in a second Major Market for a particular Licensed Product.

As further partial consideration for the grant of the rights and licenses under the License Agreement, we agreed to pay to Ligand certain one-time, non-refundable regulatory milestone payments in connection with the Licensed Products in connection with Aplindore for the indication of PD or Restless Leg Syndrome, consisting of (i) $100,000 upon submission of an application with the FDA or equivalent foreign body for a particular Licensed Product, (ii) $350,000 upon FDA approval of an application for a particular Licensed Product, (iii) $125,000 upon regulatory approval in a Major Market for a particular Licensed Product, and (iv) $125,000 upon regulatory approval in a second Major Market for a particular Licensed Product.

As further partial consideration for the grant of the rights and licenses under the License Agreement, we agreed to pay Ligand certain one-time, non-refundable commercial milestone payments in connection with the Licensed Products, consisting of (i) $10.0 million upon the achievement of $1.0 billion of cumulative worldwide net sales of Licensed Products based upon Aplindore, (ii) $10.0 million upon the achievement of $1.0 billion of cumulative worldwide net sales of Licensed Products based upon an H3 receptor antagonist, (iii) $10.0 million upon the achievement of $1.0 billion of cumulative worldwide net sales of Licensed Products based upon acetaminophen (as it may have been or may be modified for use in a product to be administered by any method in any form including, without limitation injection and intravenously, the sole active pharmaceutical ingredient of which is acetaminophen), (iv) $10.0 million upon the achievement of $1.0 billion of cumulative worldwide net sales of Licensed Products based upon CRTh2 antagonists, (v) $20.0 million upon the achievement of $2.0 billion of cumulative worldwide net sales of Licensed Products based upon Aplindore, (vi) $20.0 million upon the achievement of $2.0 billion of cumulative worldwide net sales of Licensed Products based upon an H3 receptor antagonist, (vii) $20.0 million upon the achievement of $2.0 billion of cumulative worldwide net sales of Licensed Products based upon acetaminophen (as it may have been or may be modified for use in a product to be administered by any method in any form including, without limitation, injection and intravenously, the sole active pharmaceutical ingredient of which is acetaminophen), and (viii) $20.0 million upon the achievement of $2.0 billion of cumulative worldwide net sales of Licensed Products based upon CRTh2 antagonists.

We will also pay Ligand a royalty percentage in the mid-single digits on aggregate annual net sales of Licensed Products other than in connection with Aplindore for the indication of PD or Restless Leg Syndrome in a country where such Licensed Products are covered under a licensed patent and a tiered incremental royalty in the upper single digit to lower double digit range on aggregate annual net sales of Licensed Products in connection with Aplindore for the indication of PD or Restless Leg Syndrome in a country where such Licensed Products are covered under a licensed patent. Additionally, we will pay Ligand low single digit royalties on aggregate annual net sales of Licensed Products other than in connection with Aplindore for the indication of PD or Restless Leg Syndrome in a country where such Licensed Products are not covered under a licensed patent and a tiered incremental royalty in the lower single digit to middle single digit range on aggregate annual net sales of Licensed Products in connection with Aplindore for the indication of PD or Restless Leg Syndrome in a country where such Licensed Products are not covered under a licensed patent.

Acquisition of License from iX Biopharma Europe Limited

On November 24, 2021, we entered into an exclusive license agreement (the "iX License Agreement") with iX Biopharma Europe Limited ("iX Biopharma") and a common stock purchase agreement with iX Biopharma (the "Purchase Agreement"). Pursuant to the iX License Agreement, among other things, iX Biopharma granted us an exclusive, sublicensable, perpetual, worldwide (excluding certain jurisdictions identified in the iX License Agreement) and irrevocable right and license to certain of iX Biopharma's licensed patents, know-how, and technological information, including access to iX Biopharma's research, development and manufacturing capabilities, to enable the further development, manufacture, promotion and commercialization of Wafermine™ and certain other existing and to be developed iX Biopharma wafer-based delivery technologies, now known as SLS-003, in all cases for sublingual administration of ketamine. In addition, iX Biopharma will supply us with sufficient product for the potential treatment of 400 patients, with further supplied amounts to be determined by the parties. We granted iX Biopharma an exclusive license to exploit technology developed under the iX License Agreement outside of the licensed territory and to undertake limited, non-exclusive research and development activities in the territory. We further agreed not to undertake certain activities with respect to products competitive with those licensed under the iX License Agreement during the term of the iX License Agreement.

As consideration for the license under the iX License Agreement, we agreed to (i) pay iX Biopharma an upfront fee of $9.0 million, comprised of $3.5 million in cash and $5.5 million in restricted shares (the "Shares") of our common stock, calculated in accordance with the Purchase Agreement; and (ii) pay certain development, regulatory and commercial milestones and royalty payments as further set out in the iX License Agreement.

Pursuant to the Purchase Agreement, we also agreed to reimburse iX Biopharma for the difference in value (the "Shortfall Amount") in the event the aggregate value of all of the Shares issued to iX Biopharma at the time of registration and issuance is less than $5.5 million. The Shortfall Amount could be paid in cash, additional shares of our common stock or a combination of the foregoing, depending on the size of the Shortfall Amount. We paid iX Biopharma a Shortfall Amount of $1.2 million in cash in January 2022.

Legacy Pre-Merger Programs

Pursuant to the Merger, we retained certain assets and technologies that were assets and technologies of the company that was known as "Apricus Biosciences, Inc." before the consummation of the Merger (such assets, the "Legacy Apricus Assets"). Despite that our primary operations have, post-Merger, been those of STI, and that we expect this to be the case on a going-forward basis, we may choose to monetize Legacy Apricus Assets in the future. We may also seek to monetize such assets pursuant to certain contractual obligations. Prior to the closing of the Merger, in addition to strategic efforts, we had been historically focused on the development of innovative product candidates in the areas of urology and rheumatology. We have two legacy product candidates: a product candidate in the United States intended for the topical treatment of erectile dysfunction ("ED"), which we in-licensed from Warner Chilcott Company, Inc., now a subsidiary of Allergan plc ("Allergan") (the "CVR Product Candidate"); and a product candidate which has completed a Phase IIa clinical trial for the treatment of Raynaud's Phenomenon, secondary to scleroderma, for which we own worldwide rights. At the closing of the Merger, we entered into a Contingent Value Rights Agreement (the "CVR Agreement") with STI, Richard Pascoe, as representative of holders of the contingent value rights ("CVRs"), and a rights agent. Pursuant to the CVR Agreement, each of the pre-Merger stockholders of our company received one CVR for each share of common stock held of record immediately prior to the closing of the Merger. Each CVR represents the right to receive payments based on the CVR Product Candidate and certain related assets and technologies. In particular, the holders of the CVRs will be entitled to receive 90% of any cash payments (or the fair market value of any non-cash payments) exceeding $500,000 received, during a period of ten years from the closing of the Merger, based on the sale or out-licensing of the CVR Product Candidate or related assets and technologies, including any milestone payments, less reasonable transaction expenses. We agreed to pay up to $500,000 of such Contingent Payments that we receive to a third party pursuant to a settlement agreement between us and the third party.

Patent Portfolio

As of February 24, 2023, we owned or in-licensed approximately 46 issued patents that relate to our core programs, which will expire from 2023 through 2037, approximately. Also, as of that same date, we owned or in-licensed approximately 58 patent applications that relate to our core programs, which if ultimately issued would expire as late as approximately 2043, based upon the potential expiration date of the last to expire of those patent applications.

To further strengthen our global patent position on our proprietary products under development and to expand the patent protection to other markets, we have filed foreign patent applications, many of which correspond to our issued United States patents and pending United States patent applications. These foreign filings have resulted in numerous issued patents and currently pending patent applications.

While we have obtained patents and have patent applications pending, the extent of effective patent protection in the United States and other countries is highly uncertain. No consistent policy addresses the breadth of claims allowed in or the degree of protection afforded under patents of medical and pharmaceutical companies. Patents we currently own or may obtain might not be sufficiently broad to protect us against competitors with similar technology. Any of our patents could be invalidated or circumvented.

The holders of competing patents could determine to commence a lawsuit against us and may even prevail in any such lawsuit. Litigation could result in substantial cost to and diversion of effort by us, which may harm our business. In addition, our efforts to protect or defend our proprietary rights may not be successful or, even if successful, may result in substantial cost to us.

Trademark Portfolio

As of February 24, 2023, we owned approximately 5 registered trademarks and 2 pending trademark applications worldwide. We have common law trademark rights in the unregistered marks "Seelos Therapeutics, Inc.," "Seelos" and the Seelos logo in certain jurisdictions. Vitaros is a registered trademark of Ferring in certain countries outside of the United States.

While we have obtained registered trademarks, have trademark applications pending and may have common law trademark rights where applicable, the extent of effective trademark protection in the United States and other countries is highly uncertain. Trademarks we currently own or may obtain might not be sufficiently broad to protect us against competitors. Any of our trademarks could be invalidated or circumvented.

Even where we have registered trademarks, competitors could seek to invalidate these registrations. Any such litigation could result in substantial cost to and diversion of effort by us, which may harm our business. In addition, our efforts to protect or defend our proprietary rights may not be successful or, even if successful, may result in substantial cost to us.

Governmental Regulation

Government authorities in the United States (including federal, state and local authorities) and in other countries, extensively regulate, among other things, the manufacturing, research and clinical development, marketing, labeling and packaging, storage, distribution, post-approval monitoring and reporting, advertising and promotion, pricing and export and import of pharmaceutical products, such as our products and product candidates. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Moreover, failure to comply with applicable regulatory requirements may result in, among other things, warning letters, clinical holds, civil or criminal penalties, recall or seizure of products, injunction, disbarment, partial or total suspension of production or withdrawal of the product from the market. Any agency or judicial enforcement action could have a material adverse effect on us.

United States Government Regulation

In the United States, the FDA regulates drugs and medical devices under the Federal Food, Drug, and Cosmetic Act ("FDCA"), and its implementing regulations. Drugs and devices are also subject to other federal, state and local statutes and regulations. Our product candidates are subject to regulation as combination products, which means that they are composed of both a drug product and device product. If marketed individually, each component would be subject to different regulatory pathways and reviewed by different Centers within the FDA. A combination product, however, is assigned to a Center that will have primary jurisdiction over its regulation based on a determination of the combination product's primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of our product candidates, we believe the primary mode of action is attributable to the drug component of the product, which means that the FDA's Center for Drug Evaluation and Research would have primary jurisdiction over the premarket development, review and approval of our product candidates. Accordingly, we have and plan to continue to investigate our products through the IND framework and seek approval through the NDA pathway. Based on our discussions with the FDA to date, we do not anticipate that the FDA will require a separate medical device authorization for the unit-dose dispenser to be marketed together with our product candidates, though the device component will need to comply with certain requirements applicable to devices. The process required by the FDA before our product candidates may be marketed in the United States generally involves the following:

- submission to the FDA of an IND which must become effective before human clinical trials may begin and must be updated annually;
- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA's Good Laboratory Practice regulations;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication in accordance with good clinical practices ("GCPs");
- submission to the FDA of an NDA after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the active pharmaceutical ingredient ("API"), and finished drug product are produced and tested to assess compliance with good manufacturing Practices ("cGMP") regulations; and
- FDA review and approval of an NDA prior to any commercial marketing or sale of the drug in the United States.

An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. The IND also includes results of animal studies or other human studies, as appropriate, as well as manufacturing information, analytical data and any available clinical data or literature to support the use of the investigational new drug. An IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical trials. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before clinical trials can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical trials to commence.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical trial site's institutional review board ("IRB") before the trials may be initiated, and the IRB must monitor the study until completed. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

The clinical investigation of a drug is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined. The three phases of an investigation are as follows:

- Phase I. Phase I includes the initial introduction of an investigational new drug into humans. Phase I clinical trials are typically closely monitored and may be conducted in patients with the target disease or condition or in healthy volunteers. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational drug in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness. During Phase I clinical trials, sufficient information about the investigational drug's pharmacokinetics and pharmacological effects may be obtained to permit the design of well-controlled and scientifically valid Phase II clinical trials. The total number of participants included in Phase I clinical trials varies, but is generally in the range of 20 to 80.
- Phase II. Phase II includes controlled clinical trials conducted to preliminarily or further evaluate the effectiveness of the investigational drug for a particular indication(s) in patients with the disease or condition under study, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the drug. Phase II clinical trials are typically well-controlled, closely monitored, and conducted in a limited patient population, usually involving no more than several hundred participants.
- Phase III. Phase III clinical trials are generally controlled clinical trials conducted in an expanded patient population generally at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug product, and to provide an adequate basis for product approval. Phase III clinical trials usually involve several hundred to several thousand participants.

A pivotal study is a clinical study which adequately meets regulatory agency requirements for the evaluation of a drug candidate's efficacy and safety such that it can be used to justify the approval of the product. Generally, pivotal studies are also Phase III studies but may be Phase II studies if the trial design provides a well-controlled and reliable assessment of clinical benefit, particularly in situations where there is an unmet medical need.

The FDA, the IRB or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the study. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational drug product information is submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. The application includes all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA.

Once the NDA submission has been accepted for filing, within 60 days following submission, the FDA's goal is to review applications for new molecular entities within ten months of the filing date or, if the application relates to a serious or life-threatening indication and demonstrates the potential to provide a significant improvement in safety or effectiveness over currently marketed therapies, six months from the filing date. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations.

After the FDA evaluates the NDA and conducts inspections of manufacturing facilities where the drug product and/or its active pharmaceutical ingredient will be produced, it may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A complete response letter indicates that the review cycle of the application is complete and the application is not ready for approval. A complete response letter may require additional clinical data and/or an additional pivotal Phase III clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA could also approve the NDA with a risk evaluation and mitigation strategy 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. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase IV clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. Regulatory approval of oncology products often requires that patients in clinical trials be followed for long periods to determine the overall survival benefit of the drug.

After regulatory approval of a drug product is obtained, manufacturers are required to comply with a number of post-approval requirements. The holder of an approved NDA must report, among other things, certain adverse reactions and production problems to the FDA, to provide updated safety and efficacy information, and to comply with requirements concerning advertising and promotional labeling for the approved product. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval to ensure and preserve the long-term stability of the drug product and compliance with relevant manufacturing requirements applicable to the device component. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural, substantive and record keeping requirements. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

The Hatch-Waxman Amendments

ANDA Approval Process

The Hatch-Waxman Act, established abbreviated FDA approval procedures for drugs that are shown to be equivalent to proprietary drugs previously approved by the FDA through its NDA process. Approval to market and distribute these drugs is obtained by filing an abbreviated new drug application ("ANDA") with the FDA. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. Premarket applications for generic drugs are termed abbreviated because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, a generic applicant must demonstrate that its product is bioequivalent to the innovator drug.

In certain situations, an applicant may obtain ANDA approval of a generic product with a strength or dosage form that differs from a referenced innovator drug pursuant to the filing and approval of an ANDA Suitability Petition. The FDA will approve the generic product as suitable for an ANDA application if it finds that the generic product does not raise new questions of safety and effectiveness as compared to the innovator product. A product is not eligible for ANDA approval if the FDA determines that it is not equivalent to the referenced innovator drug, if it is intended for a different use, or if it is not subject to an approved Suitability Petition. However, such a product might be approved under an NDA, with supportive data from clinical trials.

505(b)(2) NDAs

As an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments and permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant or for which the applicant has not obtained a right of reference. If the 505(b)(2) applicant can establish that reliance on FDA's previous findings of safety and effectiveness is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements, including clinical trials, to support the change from the approved branded reference drug. The FDA may then approve the new product candidate for all, or some, of the label indications for which the branded reference drug has been approved, as well as for any new indication sought by the 505(b)(2) applicant. We anticipate filing 505(b)(2) NDAs for our lead product candidates, which would rely, in part, on the FDA's previous findings of safety and efficacy of the active ingredient.

Orange Book Listing

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. The applicant may also elect to submit a ''section viii'' statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the reference NDA holder and patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant. The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired as described in further detail below.

Non-Patent Exclusivity

In addition to patent exclusivity, the holder of the NDA for the listed drug may be entitled to a period of non-patent exclusivity, during which the FDA cannot approve an ANDA or 505(b)(2) application that relies on the listed drug. For example, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon NDA approval of a new chemical entity ("NCE"), which is a drug that contains an active moiety that has not been approved by FDA in any other NDA. An ''active moiety'' is defined as the molecule or ion responsible for the drug substance's physiological or pharmacologic action. During the five-year exclusivity period, the FDA cannot accept for filing any ANDA seeking approval of a generic version of that drug or any 505(b)(2) NDA for the same active moiety and that relies on the FDA's findings regarding that drug, except that FDA may accept an application for filing after four years if the follow-on applicant makes a paragraph IV certification. A drug, including one approved under Section 505(b)(2), may obtain a three-year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. Should this occur, the FDA would be precluded from approving any ANDA or 505(b)(2) application for the protected modification until after that three-year exclusivity period has run. However, unlike NCE exclusivity, the FDA can accept an application and begin the review process during the exclusivity period.

Europe/Rest of World Government Regulation

In addition to regulations in the United States, we may be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our product candidates.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application ("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. The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with cGCPs and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug under EU regulatory systems, we must submit a marketing authorization application. The application used to file the NDA in the United States is similar to that required in Europe, with the exception of, among other things, country-specific document requirements.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with cGCPs and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

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.

Authorization Procedures in the European Union

Medicines can be authorized in the EU by using either the centralized authorization procedure or national authorization procedures.

- Centralized Procedure. Under the Centralized Procedure a so-called Community Marketing Authorization is issued by the European Commission, based on the opinion of the Committee for Medicinal Products for Human Use of the EMA. The Community Marketing Authorization is valid throughout the entire territory of the European Economic Area ("EEA") (which includes the 27 Member States of the EU plus Norway, Liechtenstein and Iceland). The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.
- For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.
- National Authorization Procedures. There are also two other possible routes to authorize medicinal products in several countries, which are available for investigational drug products that fall outside the scope of the centralized procedure:
    - Decentralized Procedure. Using the Decentralized Procedure, an applicant may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure. Under the Decentralized Procedure the applicant chooses one country as Reference Member State. The regulatory authority of the Reference Member State will then be in charge of leading the assessment of the marketing authorization application.
    - Mutual Recognition Procedure. In the Mutual Recognition Procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

In the EU, upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic product can be marketed until the expiration of the market exclusivity. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

Other Health Care Laws

We may also be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments where we may market our product candidates, if approved. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, physician sunshine and privacy and security laws and regulations. The federal Anti-Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. The Anti-Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the Anti-Kickback Statute to reach large settlements with healthcare companies based on sham consulting and other financial arrangements with physicians. 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. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. The majority of states also have anti-kickback laws which establish similar prohibitions and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Additionally, the civil False Claims Act prohibits knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the United States government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the United States, for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") also created new federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

There has also been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, (collectively, "the Affordable Care Act"), among other things, imposed new reporting requirements on drug manufacturers for payments made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information may result in civil monetary penalties of up to an aggregate of approximately $0.2 million per year (or up to an aggregate of $1.1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Drug manufacturers are required to submit reports to the government by the 90th day of each calendar year. Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of marketing expenditures and pricing information as well as gifts, compensation and other remuneration to physicians.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act ("HITECH"), and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, 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 attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

Coverage and Reimbursement

Sales of our product candidates, once 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 programs, private health insurers and managed care organizations. Third-party payors generally decide which drugs they will cover and establish certain reimbursement levels for such drugs. In particular, in the United States, private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Sales of our products and product candidates, if approved, will therefore depend substantially on the extent to which the costs of products and our product candidates will be paid by third-party payors. Additionally, the market for our products and product candidates will depend significantly on access to third-party payors' formularies without prior authorization, step therapy, or other limitations such as approved lists of treatments for which third-party payors provide coverage and reimbursement. Additionally, coverage and reimbursement for therapeutic products can differ significantly from payor to payor. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will be a time-consuming process.

In addition, the United States government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our future net revenue and results. For example, on August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022, which, among other things, includes policies that are designed to have a direct impact on drug prices and reduce drug spending by the federal government, which shall take effect in 2023. Under the Inflation Reduction Act, Congress authorized Medicare beginning in 2026 to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars. This provision is limited in terms of the number of pharmaceuticals whose prices can be negotiated in any given year and it only applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years. Drugs and biologics that have been approved for a single rare disease or condition are categorically excluded from price negotiation. Further, the new legislation provides that if pharmaceutical companies raise prices in Medicare faster than the rate of inflation, they must pay rebates back to the government for the difference. The new law also caps Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at $2,000 a year. Decreases in third-party reimbursement for our products and product candidates or a decision by a third-party payor to not cover our products or product candidates could reduce physician usage of our products and product candidates, if approved, and have a material adverse effect on our sales, results of operations and financial condition.

Health Care Reform

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. There have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs.

In particular, in the United States, the Affordable Care Act has had, and is expected to continue to have, a significant impact on the healthcare industry. The Affordable Care Act was designed to expand coverage for the uninsured while at the same time containing overall healthcare costs. The Affordable Care Act, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts, which, through subsequent legislative amendments, was increased to 70%, off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. Substantial new provisions affecting compliance were also enacted, which may require us to modify our business practices with healthcare providers and entities.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act. Most recently, the Tax Cuts and Jobs Act was enacted, which, among other things, removes penalties for not complying with Affordable Care Act's individual mandate to carry health insurance. There is still uncertainty with respect to the impact President Biden's administration and the U.S. Congress may have, if any, and any changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the Affordable Care Act.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2025 unless additional Congressional action is taken. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, reform government program reimbursement methodologies. Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Employees

As of February 24, 2023, we had 16 employees, 15 of which are full-time employees, and all of whom are in the United States. Our organization will rely primarily on outsourcing research, development and clinical trial activities, and manufacturing operations, as well as other functions critical to our business. We believe this approach enhances our ability to focus on our core product opportunities, allocate resources efficiently to different projects and allocate internal resources more effectively. None of our employees are represented by a collective bargaining agreement. We believe that we have a good relationship with our employees.

Corporate Information

We were incorporated under the laws of the State of Nevada in 1987, as NexMed, Inc. On September 10, 2010, we changed our name to "Apricus Biosciences, Inc." On January 24, 2019, we completed the Merger with STI (formerly known as Seelos Therapeutics, Inc.), a Delaware corporation, and, upon completion of the Merger, we changed our name to "Seelos Therapeutics, Inc." Shares of our common stock commenced trading on the Nasdaq Capital Market under the ticker symbol "SEEL" as of market open on January 24, 2019.

Available Information

We file annual, quarterly and current reports, proxy statements and other information with the SEC, and we have an Internet website address at http://www.seelostherapeutics.com. We make available free of charge on our Internet website address our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Sections 13(a) or 15(d) of the Exchange Act as well as our proxy statements as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. You may also obtain copies of such documents from the SEC's website at http://www.sec.gov.

ITEM 1A. RISK FACTORS

We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. Certain factors may have a material adverse effect on our business, prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this Annual Report on Form 10-K and our other public filings with the SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

Risk Factor Summary

Below is a summary of the principal factors that make an investment in our securities speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below and should be carefully considered, together with all of the other information appearing in or incorporated by reference into this Annual Report on Form 10-K and our other public filings with the SEC before making an investment decision regarding our common stock. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

- We are a clinical-stage company, we have a very limited operating history, are not currently profitable, do not expect to become profitable in the near future and may never become profitable.
- We are dependent on the success of one or more of our current product candidates and we cannot be certain that any of them will receive regulatory approval or be commercialized.
- If development of our product candidates does not produce favorable results, or encounters challenges, we and our collaborators, if any, may be unable to commercialize these products.
- We expect to continue to incur significant research and development expenses, which may make it difficult for us to attain profitability.
- Our debt agreement contains restrictive and financial covenants that may limit our operating flexibility and the failure to comply with such covenants could cause our outstanding debt to become immediately payable.
- Given our lack of current cash flow, we may need to raise additional capital; however, it may be unavailable to us or, even if capital is obtained, may cause dilution or place significant restrictions on our ability to operate our business. If we fail to raise the necessary additional capital, we may be unable to complete the development and commercialization of our product candidates, or continue our development programs.
- Our product candidates may cause undesirable side effects that could delay or prevent their regulatory approval or commercialization or have other significant adverse implications on our business, financial condition and results of operations.
- Interim and preliminary results from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to additional audit, validation and verification procedures that could result in material changes in the final data.
- Delays in the commencement or completion of clinical trials could result in increased costs to us and delay our ability to establish strategic collaborations.
- The COVID-19 pandemic, and any other pandemic, epidemic or outbreak of an infectious disease may materially and adversely affect our business and operations.
- Results of earlier clinical trials may not be predictive of the results of later-stage clinical trials.
- We intend to rely on third parties to conduct our preclinical studies and clinical trials and perform other tasks. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business, financial condition and results of operations could be substantially harmed.
- Our product candidates are subject to extensive regulation under the U.S. Food and Drug Administration ("FDA"), the European Medicines Agency (the "EMA") or comparable foreign authorities, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.
- If our competitors have product candidates that are approved faster, marketed more effectively, are better tolerated, have a more favorable safety profile or are demonstrated to be more effective than ours, our commercial opportunity may be reduced or eliminated.
- We rely completely on third parties to manufacture our preclinical and clinical drug supplies, and our business, financial condition and results of operations could be harmed if those third parties fail to provide us with sufficient quantities of drug product, or fail to do so at acceptable quality levels or prices.
- The commercial success of our product candidates depends upon their market acceptance among physicians, patients, healthcare payors and the medical community.
- If we fail to retain current members of our senior management and scientific personnel, or to attract and keep additional key personnel, we may be unable to successfully develop or commercialize our product candidates.
- We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

- If we fail to comply with our obligations in the agreements under which we in-license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.
- We may not be able to protect our proprietary or licensed technology in the marketplace.
- The market price of our common stock is expected to be volatile.

Risk Factors

Risks Related to the Company

We are a clinical-stage company, we have a very limited operating history, are not currently profitable, do not expect to become profitable in the near future and may never become profitable.

We are a clinical-stage biopharmaceutical company. Since our incorporation, we have focused primarily on the development and acquisition of clinical-stage therapeutic candidates. All of our therapeutic candidates are in the clinical development stage and none of our pipeline therapeutic candidates have been approved for marketing or are being marketed or commercialized.

As a result, we have no meaningful historical operations upon which to evaluate our business and prospects and have not yet demonstrated an ability to obtain marketing approval for any of our product candidates or successfully overcome the risks and uncertainties frequently encountered by companies in the biopharmaceutical industry. We also have generated minimal revenues from collaboration and licensing agreements and no revenues from product sales to date and continue to incur significant research and development and other expenses. As a result, we have not been profitable and have incurred significant operating losses in every reporting period since our inception. We have incurred an accumulated deficit of $214.7 million from our inception through December 31, 2022.

For the foreseeable future, we expect to continue to incur losses, which will increase significantly from historical levels as we expand our drug development activities, seek partnering and/or regulatory approvals for our product candidates and begin to commercialize them if they are approved by the FDA, the EMA or comparable foreign authorities. Even if we succeed in developing and commercializing one or more product candidates, we may never become profitable.

We are dependent on the success of one or more of our current product candidates and we cannot be certain that any of them will receive regulatory approval or be commercialized.

We have spent significant time, money and effort on the licensing and development of our core assets, SLS-002 and SLS-005, and our other earlier-stage assets, SLS-004, SLS-006, SLS-007, SLS-008, SLS-010 and SLS-012. To date, no pivotal clinical trials designed to provide clinically and statistically significant proof of efficacy, or to provide sufficient evidence of safety to justify approval, have been completed with any of our pipeline product candidates. All of our product candidates will require additional development, including clinical trials as well as further preclinical studies to evaluate their toxicology, carcinogenicity and pharmacokinetics and optimize their formulation, and regulatory clearances before they can be commercialized. Positive results obtained during early development do not necessarily mean later development will succeed or that regulatory clearances will be obtained. Our drug development efforts may not lead to commercial drugs, either because our product candidates may fail to be safe and effective or because we have inadequate financial or other resources to advance our product candidates through the clinical development and approval processes. If any of our product candidates fail to demonstrate safety or efficacy at any time or during any phase of development, we would experience potentially significant delays in, or be required to abandon, development of the product candidate.

We do not anticipate that any of our current product candidates will be eligible to receive regulatory approval from the FDA, the EMA or comparable foreign authorities and begin commercialization for a number of years, if ever. Even if we ultimately receive regulatory approval for any of these product candidates, we or our potential future partners, if any, may be unable to commercialize them successfully for a variety of reasons. These include, for example, the availability of alternative treatments, lack of cost-effectiveness, the cost of manufacturing the product on a commercial scale and competition with other drugs. The success of our product candidates may also be limited by the prevalence and severity of any adverse side effects. If we fail to commercialize one or more of our current product candidates, we may be unable to generate sufficient revenues to attain or maintain profitability, and our financial condition and stock price may decline.

If development of our product candidates does not produce favorable results, or encounters challenges, we and our collaborators, if any, may be unable to commercialize these products.

To receive regulatory approval for the commercialization of our core assets, SLS-002 and SLS-005, and our earlier-stage assets, SLS-004, SLS-006, SLS-007, SLS-008, SLS-010 and SLS-012, or any other product candidates that we may develop, adequate and well-controlled clinical trials must be conducted to demonstrate safety and efficacy in humans to the satisfaction of the FDA, the EMA and comparable foreign authorities. In order to support marketing approval, these agencies typically require successful results in one or more Phase III clinical trials, which our current product candidates have not yet reached and may never reach. The development process is expensive, can take many years and has an uncertain outcome. Failure can occur at any stage of the process. We may experience numerous unforeseen events during, or as a result of, the development process that could delay or prevent commercialization of our current or future product candidates, including the following:

- clinical trials may produce negative or inconclusive results;
- preclinical studies conducted with product candidates during clinical development to, among other things, evaluate their toxicology, carcinogenicity and pharmacokinetics and optimize their formulation may produce unfavorable results;
- we or our contract manufacturers may encounter manufacturing challenges or the FDA may raise concerns regarding Chemistry, Manufacturing, and Controls (CMC) data or GMP compliance, or biocompatibility or drug-device interaction concerns for our combination product candidates;
- patient recruitment and enrollment in clinical trials may be slower than we anticipate;
- costs of development may be greater than we anticipate;
- our product candidates may cause undesirable side effects that delay or preclude regulatory approval or limit their commercial use or market acceptance, if approved;
- collaborators who may be responsible for the development of our product candidates may not devote sufficient resources to these clinical trials or other preclinical studies of these candidates or conduct them in a timely manner; or
- we may face delays in obtaining regulatory approvals to commence one or more clinical trials.

Success in early development does not mean that later development will be successful because, for example, product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy despite having progressed through initial clinical trials.

We have licensed or acquired all of the intellectual property related to our product candidates from third parties. All clinical trials, preclinical studies and other analyses performed to date with respect to our product candidates have been conducted by their original owners. Therefore, as a company, we have limited experience in conducting clinical trials for our product candidates. Since our experience with our product candidates is limited, we will need to train our existing personnel and hire additional personnel in order to successfully administer and manage our clinical trials and other studies as planned, which may result in delays in completing such planned clinical trials and preclinical studies. Moreover, to date our product candidates have been tested in less than the number of patients that will likely need to be studied to obtain regulatory approval. The data collected from clinical trials with larger patient populations may not demonstrate sufficient safety and efficacy to support regulatory approval of these product candidates.

We currently do not have strategic collaborations in place for clinical development of any of our current product candidates, except for our collaborative agreement with Team Sanfilippo Foundation (“TSF”), which we assumed in connection with the asset purchase agreement with Bioblast Pharma Ltd. for IV Trehalose, which is now known as SLS-005. Therefore, in the future, we or any potential future collaborative partner will be responsible for establishing the targeted endpoints and goals for development of our product candidates. These targeted endpoints and goals may be inadequate to demonstrate the safety and efficacy levels required for regulatory approvals. Even if we believe data collected during the development of our product candidates are promising, such data may not be sufficient to support marketing approval by the FDA, the EMA or comparable foreign authorities. Further, data generated during development can be interpreted in different ways, and the FDA, the EMA or comparable foreign authorities may interpret such data in different ways than us or our collaborators. Our failure to adequately demonstrate the safety and efficacy of our product candidates would prevent our receipt of regulatory approval, and ultimately the potential commercialization of these product candidates.

Since we do not currently possess the resources necessary to independently develop and commercialize our product candidates or any other product candidates that we may develop, we may seek to enter into collaborative agreements to assist in the development and potential future commercialization of some or all of these assets as a component of our strategic plan. However, our discussions with potential collaborators may not lead to the establishment of collaborations on acceptable terms, if at all, or it may take longer than expected to establish new collaborations, leading to development and potential commercialization delays, which would adversely affect our business, financial condition and results of operations.

We expect to continue to incur significant research and development expenses, which may make it difficult for us to attain profitability.

We expect to expend substantial funds in research and development, including preclinical studies and clinical trials of our product candidates, and to manufacture and market any product candidates in the event they are approved for commercial sale. We also may need additional funding to develop or acquire complementary companies, technologies and assets, as well as for working capital requirements and other operating and general corporate purposes. Moreover, our planned increases in staffing will dramatically increase our costs in the near and long-term.

However, our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. Due to our limited financial and managerial resources, we must focus on a limited number of research programs and product candidates and on specific indications. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Because the successful development of our product candidates is uncertain, we are unable to precisely estimate the actual funds we will require to develop and potentially commercialize them. In addition, we may not be able to generate sufficient revenue, even if we are able to commercialize any of our product candidates, to become profitable.

Our debt agreement contains restrictive and financial covenants that may limit our operating flexibility and the failure to comply with such covenants could cause our outstanding debt to become immediately payable.

On November 23, 2021, we issued and sold to Lind Global Asset Management V, LLC ("Lind") a convertible promissory note in an aggregate principal amount of $22.0 million for an aggregate purchase price of $20.0 million (the "Convertible Promissory Note"). The Convertible Promissory Note contains certain restrictive covenants and event of default provisions, including restrictions on certain sales or other dispositions of company assets, restrictions on entering into certain variable-rate transactions and a covenant requiring us to maintain an aggregate minimum balance of $10.0 million or more in cash and cash equivalents through June 30, 2023 and an aggregate minimum balance of $12.5 million on or after July 1, 2023. In the event we fail to meet the minimum cash balance as required under the Convertible Promissory Note, and if we are unable to cure such default within fifteen days from its occurrence or otherwise obtain a waiver from Lind or amend the terms of the Convertible Promissory Note, we would trigger a default under the Convertible Promissory Note. If we are not able to comply or regain compliance with any of the covenants in, or otherwise trigger a default under, the Convertible Promissory Note, Lind could declare the Convertible Promissory Note immediately due and payable, which would require us to pay 120% of the outstanding principal amount of the Convertible Promissory Note and would have a material adverse effect on our liquidity, financial condition, operating results, business and prospects, and could cause the price of our common stock to decline. In addition, since the borrowings under the Convertible Promissory Note are secured by a first priority lien on our assets, Lind would be able to foreclose on our assets if we do not cure any default or pay any amounts due and payable under the Convertible Promissory Note.

Given our lack of current cash flow, we may need to raise additional capital; however, it may be unavailable to us or, even if capital is obtained, may cause dilution or place significant restrictions on our ability to operate our business. If we fail to raise the necessary additional capital, we may be unable to complete the development and commercialization of our product candidates, or continue our development programs.

As of December 31, 2022, we had a cash balance of approximately $15.5 million. Since we will be unable to generate sufficient, if any, cash flow to fund our operations for the foreseeable future, we may need to seek additional equity or debt financing to provide the capital required to maintain or expand our operations.

As a result of our recurring losses from operations, there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, which raises substantial doubt about our ability to continue as a going concern. If we are unsuccessful in our efforts to raise outside financing, we may be required to significantly reduce or cease operations. The report of our independent registered public accounting firm on our audited financial statements for the year ended December 31, 2022 included a "going concern" explanatory paragraph indicating that our recurring losses from operations raise substantial doubt about our ability to continue as a going concern.

We currently have an effective shelf registration statement on Form S-3 filed with the SEC. We may use the shelf registration statement on Form S-3 to offer from time to time any combination of debt securities, common and preferred stock and warrants. Moreover, we have the ability to sell up to $50.0 million of additional shares of our common stock to the public through an "at the market" offering pursuant to the Sales Agreement we entered into with Jefferies, LLC on May 12, 2022. As of the date hereof, a total of $94.6 million of securities remains available for issuance pursuant to the shelf registration statement (inclusive of the $49.5 million that remained allocated to sales of shares pursuant to the Sales Agreement as of such date).

There can be no assurance that we will be able to raise sufficient additional capital on acceptable terms or at all. In addition, the impact of the COVID-19 pandemic on the global financial markets may reduce our ability to access capital, which could negatively affect our liquidity and ability to continue as a going concern. If such additional financing is not available on satisfactory terms, or is not available in sufficient amounts, we may be required to delay, limit or eliminate the development of business opportunities and our ability to achieve our business objectives, our competitiveness, and our business, financial condition and results of operations will be materially adversely affected. In addition, we may be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our inability to fund our business could lead to the loss of your investment.

Our future capital requirements will depend on many factors, including, but not limited to:

- the scope, rate of progress, results and cost of our clinical trials, preclinical studies and other related activities;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the timing of, and the costs involved in, obtaining regulatory approvals for any of our current or future product candidates;
- the number and characteristics of the product candidates we seek to develop or commercialize;
- the cost of manufacturing clinical supplies, and establishing commercial supplies, of our product candidates;
- the cost of commercialization activities if any of our current or future product candidates are approved for sale, including marketing, sales and distribution costs;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing possible patent claims, including litigation costs and the outcome of any such litigation.

If we raise additional capital by issuing equity securities, the percentage ownership of our existing stockholders may be reduced, and accordingly these stockholders may experience substantial dilution. We may also issue equity securities that provide for rights, preferences and privileges senior to those of our common stock. Given our need for cash and that equity issuances are the most common type of fundraising for similarly situated companies, the risk of dilution is particularly significant for our stockholders.

In addition, debt financing may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may be secured by all or a portion of our assets. For example, we granted to Lind, as the holder of the Convertible Promissory Note, a first priority lien on our assets and properties and the Convertible Promissory Note includes restrictive covenants and event of default provisions, including restrictions on certain sales or other dispositions of company assets, restrictions on entering into certain variable-rate transactions and a covenant requiring us to maintain an aggregate minimum balance of $10.0 million or more in cash and cash equivalents through June 30, 2023 and an aggregate minimum balance of $12.5 million on or after July 1, 2023. Our inability to raise capital when needed may harm our business, financial condition and results of operations, and could cause our stock price to decline or require that we wind down our operations altogether.

Our product candidates may cause undesirable side effects that could delay or prevent their regulatory approval or commercialization or have other significant adverse implications on our business, financial condition and results of operations.

Undesirable side effects observed in clinical trials or in supportive preclinical studies with our product candidates could interrupt, delay or halt their development and could result in the denial of regulatory approval by the FDA, the EMA or comparable foreign authorities for any or all targeted indications or adversely affect the marketability of any such product candidates that receive regulatory approval. In turn, this could eliminate or limit our ability to commercialize our product candidates.

Our product candidates may exhibit adverse effects in preclinical toxicology studies and adverse interactions with other drugs. There are also risks associated with additional requirements the FDA, the EMA or comparable foreign authorities may impose for marketing approval with regard to a particular disease.

Our product candidates may require a risk management program that could include patient and healthcare provider education, usage guidelines, appropriate promotional activities, a post-marketing observational study, and ongoing safety and reporting mechanisms, among other requirements. Prescribing could be limited to physician specialists or physicians trained in the use of the drug, or could be limited to a more restricted patient population. Any risk management program required for approval of our product candidates could potentially have an adverse effect on our business, financial condition and results of operations.

Undesirable side effects involving our product candidates may have other significant adverse implications on our business, financial condition and results of operations. For example:

- we may be unable to obtain additional financing on acceptable terms, if at all;
- our collaborators may terminate any development agreements covering these product candidates;
- if any development agreements are terminated, we may determine not to further develop the affected product candidates due to resource constraints and may not be able to establish additional collaborations for their further development on acceptable terms, if at all;
- if we were to later continue the development of these product candidates and receive regulatory approval, earlier findings may significantly limit their marketability and thus significantly lower our potential future revenues from their commercialization;
- we may be subject to product liability or stockholder litigation; and
- we may be unable to attract and retain key employees.

In addition, if any of our product candidates receive marketing approval and we or others later identify undesirable side effects caused by the product:

- regulatory authorities may withdraw their approval of the product, or we or our partners may decide to cease marketing and sale of the product voluntarily;
- we may be required to change the way the product is administered, conduct additional clinical trials or preclinical studies regarding the product, change the labeling of the product, or change the product's manufacturing facilities; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product and could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating significant revenues from the sale of the product.

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

From time to time, we may publish interim data, including interim top-line results or preliminary results from our clinical trials. Any interim data and other results from our clinical trials may materially change as more patient data become available. Preliminary or top-line results also remain subject to audit, validation and verification procedures that may result in the final data being materially different from the interim and preliminary data we previously published. As a result, interim and preliminary data may not be predictive of final results and should be viewed with caution until the final data are available. We may also arrive at different conclusions, or considerations may qualify such results, once we have received and fully evaluated additional data. Differences between preliminary or interim data and final data could adversely affect our business.

Our efforts to discover product candidates beyond our current product candidates may not succeed, and any product candidates we recommend for clinical development may not actually begin clinical trials.

We intend to use our technology, including our licensed technology, knowledge and expertise to develop novel drugs to address some of the world's most widespread and costly central nervous system, respiratory and other disorders, including orphan indications. We intend to expand our existing pipeline of core assets by advancing drug compounds from current ongoing discovery programs into clinical development. However, the process of researching and discovering drug compounds is expensive, time-consuming and unpredictable. Data from our current preclinical programs may not support the clinical development of our lead compounds or other compounds from these programs, and we may not identify any additional drug compounds suitable for recommendation for clinical development. Moreover, any drug compounds we recommend for clinical development may not demonstrate, through preclinical studies, indications of safety and potential efficacy that would support advancement into clinical trials. Such findings would potentially impede our ability to maintain or expand our clinical development pipeline. Our ability to identify new drug compounds and advance them into clinical development also depends upon our ability to fund our research and development operations, and we cannot be certain that additional funding will be available on acceptable terms, or at all.

Delays in the commencement or completion of clinical trials could result in increased costs to us and delay our ability to establish strategic collaborations.

Delays in the commencement or completion of clinical trials could significantly impact our drug development costs. We do not know whether planned clinical trials will begin on time or be completed on schedule, if at all. The commencement of clinical trials can be delayed for a variety of reasons, including, but not limited to, delays related to:

- obtaining regulatory approval to commence one or more clinical trials;
- reaching agreement on acceptable terms with prospective third-party contract research organizations ("CROs") and clinical trial sites;
- manufacturing sufficient quantities of a product candidate or other materials necessary to conduct clinical trials;
- obtaining institutional review board approval to conduct one or more clinical trials at a prospective site;
- recruiting and enrolling patients to participate in one or more clinical trials; and
- the failure of our collaborators to adequately resource our product candidates due to their focus on other programs or as a result of general market conditions.

In addition, once a clinical trial has begun, it may be suspended or terminated by us, our collaborators, the institutional review boards or data safety monitoring boards charged with overseeing our clinical trials, the FDA, the EMA or comparable foreign authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- inspection of the clinical trial operations or clinical trial site by the FDA, the EMA or comparable foreign authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues; or
- lack of adequate funding to continue the clinical trial.

If we experience delays in the completion, or termination, of any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to commence product sales and generate product revenues from any of our product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs and slow down our product candidate development and approval process. Delays in completing our clinical trials could also allow our competitors to obtain marketing approval before we do or shorten the patent protection period during which we may have the exclusive right to commercialize our product candidates. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

The COVID-19 pandemic, and any other pandemic, epidemic or outbreak of an infectious disease, may materially and adversely affect our business and operations.

The COVID-19 pandemic is continuing to affect the United States and global economies and may affect our operations and those of third parties on which we rely, including by causing disruptions in the supply of our product candidates and the conduct of future clinical trials. Additionally, while the potential economic impact brought by, and the duration of the COVID-19 pandemic, are difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity. In addition, the loss of any of our employees as a result of COVID-19 or another pandemic may have a material adverse effect on our operations. Any continued and prolonged public health crisis such as the COVID-19 pandemic could have a material negative impact on our business, financial condition, and operating results.

Results of earlier clinical trials may not be predictive of the results of later-stage clinical trials.

The results of preclinical studies and early clinical trials of product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier studies. Similarly, our future clinical trial results may not be successful for these or other reasons.

This product candidate development risk is heightened by any changes in the planned clinical trials compared to the completed clinical trials. As product candidates are developed through preclinical to early to late stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and methods of administration, are altered along the way in an effort to optimize processes and results. While these types of changes are common and are intended to optimize the product candidates for late stage clinical trials, approval and commercialization, such changes carry the risk that they will not achieve these intended objectives. In addition, nonclinical studies may be requested or required even after clinical trials have been commenced or completed.

Any of these changes could make the results of our planned clinical trials or other future clinical trials we may initiate less predictable and could cause our product candidates to perform differently, including causing toxicities, which could delay completion of our clinical trials, delay approval of our product candidates, and/or jeopardize our ability to commence product sales and generate revenues.

If we experience delays in the enrollment of patients in our clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other regulatory authorities. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

If we fail to enroll and maintain the number of patients for which the clinical trial was designed, the statistical power of that clinical trial may be reduced, which would make it harder to demonstrate that the product candidate being tested in such clinical trial is safe and effective. Additionally, enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

We intend to rely on third parties to conduct our preclinical studies and clinical trials and perform other tasks. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business, financial condition and results of operations could be substantially harmed.

We intend to rely upon third-party CROs, medical institutions, clinical investigators and contract laboratories to monitor and manage data for our ongoing preclinical and clinical programs. Nevertheless, we maintain responsibility for ensuring that each of our clinical trials and preclinical studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with current requirements on good manufacturing practices ("cGMP") good clinical practices ("GCP") and good laboratory practice ("GLP"), which are a collection of laws and regulations enforced by the FDA, the EMA and comparable foreign authorities for all of our product candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections of preclinical study and clinical trial sponsors, principal investigators, preclinical study and clinical trial sites, and other contractors. If we or any of our CROs or vendors fails to comply with applicable regulations, the data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign authorities may require us to perform additional preclinical studies and clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced consistent with cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the development and regulatory approval processes.

We may not be able to enter into arrangements with CROs on commercially reasonable terms, or at all. In addition, our CROs will not be our employees, and except for remedies available to us under our agreements with such CROs, we will not be able to control whether or not they devote sufficient time and resources to our ongoing preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. CROs may also generate higher costs than anticipated. As a result, our business, financial condition and results of operations and the commercial prospects for our product candidates could be materially and adversely affected, our costs could increase, and our ability to generate revenue could be delayed.

Switching or adding additional CROs, medical institutions, clinical investigators or contract laboratories involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work replacing a previous CRO. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. There can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition or results of operations.

Our product candidates are subject to extensive regulation under the FDA, the EMA or comparable foreign authorities, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, export, marketing and distribution of our product candidates are subject to extensive regulation by the FDA and other U.S. regulatory agencies, the EMA or comparable authorities in foreign markets. In the U.S., neither we nor our collaborators are permitted to market our product candidates until we or our collaborators receive approval of a new drug application ("NDA") from the FDA or receive similar approvals abroad. The process of obtaining these approvals is expensive, often takes many years, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. Approval policies or regulations may change and may be influenced by the results of other similar or competitive products, making it more difficult for us to achieve such approval in a timely manner or at all. Any guidance that may result from recent FDA advisory panel discussions may make it more expensive to develop and commercialize such product candidates. In addition, as a company, we have not previously filed NDAs with the FDA or filed similar applications with other foreign regulatory agencies. This lack of experience may impede our ability to obtain FDA or other foreign regulatory agency approval in a timely manner, if at all, for our product candidates for which development and commercialization is our responsibility.

Despite the time and expense invested, regulatory approval is never guaranteed. The FDA, the EMA or comparable foreign authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- a product candidate may not be deemed safe or effective;
- agency officials of the FDA, the EMA or comparable foreign authorities may not find the data from non-clinical or preclinical studies and clinical trials generated during development to be sufficient;
- the FDA, the EMA or comparable foreign authorities may not approve our third-party manufacturers' processes or facilities;
- the FDA, the EMA or a comparable foreign authority may change its approval policies or adopt new regulations; or
- our inability to obtain these approvals would prevent us from commercializing our product candidates.

We are pursuing the FDA 505(b)(2) NDA pathway for our lead product candidate, SLS-002, which presents certain additional development and commercialization risks as compared to a conventional 505(b)(1) NDA for an innovator product candidate. We may pursue this pathway for other product candidates as well.

For our lead product candidate (SLS-002) we are pursuing development in order to seek potential FDA approval under an abbreviated regulatory pathway called a 505(b)(2) NDA, which permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. We may also pursue this pathway for other of our product candidates. Section 505(b)(2), if applicable to us for a particular product candidate, would allow an NDA we submit to the FDA to rely, in part, on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for a product candidate by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval.

Even if the FDA allows us to rely on the 505(b)(2) regulatory pathway, there is no assurance that such marketing approval will be obtained in a timely manner, or at all. The FDA may require us to perform additional nonclinical studies and clinical trials, and conduct other development work, to support any change from the reference listed drug (including with respect to the route of administration and drug delivery method and device), which presents uncertainty about the data that may ultimately be necessary and could be time-consuming and substantially delay our application for or potential receipt of marketing approval.

Even if we are able to utilize the 505(b)(2) regulatory pathway, a drug approved via this pathway may be subject to the same post-approval limitations, conditions and requirements as any other drug, including, for example a Risk Evaluation and Mitigation Strategy ("REMS"), which we anticipate will be required for our lead product candidate.

Also, as has been the experience of others in our industry, our competitors may file citizens' petitions with the FDA to contest approval of our NDA, which may delay or even prevent the FDA from approving any NDA that we submit under the 505(b)(2) regulatory pathway. If an FDA decision or action relative to our product candidate, or the FDA's interpretation of Section 505(b)(2) more generally, is successfully challenged, it could result in delays or even prevent the FDA from approving a 505(b)(2) application for such product candidate.

In addition, we may face Hatch-Waxman litigation in relation to our NDAs submitted under the 505(b)(2) regulatory pathway, which may further delay or prevent the approval of our product candidate. The pharmaceutical industry is highly competitive, and 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a 505(b)(2) NDA. If the previously approved drugs referenced in an applicant's 505(b)(2) NDA are protected by patent(s) listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations publication, or the Orange Book, the 505(b)(2) applicant is required to make a claim after filing its NDA that each such patent is invalid, unenforceable or will not be infringed. The patent holder may thereafter bring suit for patent infringement, which will trigger a mandatory 30-month delay (or the shorter of dismissal of the lawsuit or expiration of the patent(s)) in approval of the 505(b)(2) NDA application.

If the FDA determines that our 505(b)(2) regulatory pathway is not viable for SLS-002 or any other applicable product candidate for any reason, we would need to reconsider our plans and might not be able to commercialize any such product candidate in a cost-efficient manner, or at all. If we were to pursue approval under the 505(b)(1) NDA pathway, we would be subject to more extensive requirements and risks such as conducting additional clinical trials, providing additional data and information or meeting additional standards for marketing approval. As a result, the time and financial resources required to obtain marketing approval for our product candidates would likely increase substantially and further complications and risks associated with our product candidates may arise. Also, new competing products may reach the market faster than ours, which may materially and adversely affect our competitive position, business and prospects.

Even if our product candidates receive regulatory approval in the U.S., we may never receive approval or commercialize our products outside of the U.S.

In order to market any products outside of the U.S., we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the U.S. as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay seeking or obtaining such approval would impair our ability to develop foreign markets for our product candidates.

Even if any of our product candidates receive regulatory approval, our product candidates may still face future development and regulatory difficulties.

If any of our product candidates receive regulatory approval, the FDA, the EMA or comparable foreign authorities may still impose significant restrictions on the indicated uses or marketing of the product candidates or impose ongoing requirements for potentially costly post-approval studies and trials. In addition, regulatory agencies subject a product, our manufacturer and the manufacturer's facilities to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, our collaborators or us, including requiring withdrawal of the product from the market. Our product candidates will also be subject to ongoing FDA, EMA or comparable foreign authorities' requirements for the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. If our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or other notices of possible violations;
- impose civil or criminal penalties or fines or seek disgorgement of revenue or profits;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us or our collaborators;
- withdraw any regulatory approvals;
- impose restrictions on operations, including costly new manufacturing requirements, or shut down our manufacturing operations; or
- seize or detain products or require a product recall.

The FDA, the EMA and comparable foreign authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA, the EMA and comparable foreign authorities strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA, the EMA or comparable foreign authorities as reflected in the product's approved labeling. If we receive marketing approval for our product candidates for our proposed indications, physicians may nevertheless use our products for their patients in a manner that is inconsistent with the approved label, if the physicians personally believe in their professional medical judgment that our products could be used in such manner. However, if we are found to have promoted our products for any off-label uses, the federal government could levy civil, criminal or administrative penalties, and seek fines against us. Such enforcement has become more common in the industry. The FDA, the EMA or comparable foreign authorities could also request that we enter into a consent decree or a corporate integrity agreement, or seek a permanent injunction against us under which specified promotional conduct is monitored, 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, financial condition and results of operations.

If our competitors have product candidates that are approved faster, marketed more effectively, are better tolerated, have a more favorable safety profile or are demonstrated to be more effective than ours, our commercial opportunity may be reduced or eliminated.

The biopharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including commercial biopharmaceutical enterprises, academic institutions, government agencies and private and public research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, clinical trials, regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our competitors may succeed in developing technologies and therapies that are more effective, better tolerated or less costly than any which we are developing, or that would render our product candidates obsolete and noncompetitive. Even if we obtain regulatory approval for any of our product candidates, our competitors may succeed in obtaining regulatory approvals for their products earlier than we do. We will also face competition from these third parties in recruiting and retaining qualified scientific and management personnel, in establishing clinical trial sites and patient registration for clinical trials, and in acquiring and in-licensing technologies and products complementary to our programs or advantageous to our business.

The key competitive factors affecting the success of each of our product candidates, if approved, are likely to be its efficacy, safety, tolerability, frequency and route of administration, convenience and price, the level of branded and generic competition and the availability of coverage and reimbursement from government and other third-party payors.

The pharmaceutical market for the treatment of major depressive disorder includes selective serotonin reuptake inhibitors ("SSRIs"), serotonin and norepinephrine reuptake inhibitors ("SNRIs") and atypical antipsychotics. A number of these marketed antidepressants will be generic, and would be key competitors to SLS-002. These products include Forest Laboratory's Lexapro/Cipralex (escitalopram) and Viibryd (vilazodone), Pfizer, Inc.'s Zoloft (sertraline), Effexor (venlafaxine) and Pristiq (desvenlafaxine), GlaxoSmithKline plc's Paxil/Seroxat (paroxetine), Eli Lilly and Company's Prozac (fluoxetine) and Cymbalta (duloxetine), AstraZeneca plc's Seroquel (quetiapine) and Bristol-Myers Squibb Company's Abilify (aripiprazole), among others.

Patients with treatment-resistant depression often require treatment with several antidepressants, such as an SSRI or SNRI, combined with an "adjunct" therapy such as an antipsychotic compound, such as AstraZeneca plc's Seroquel (quetiapine) and Bristol-Myers Squibb Company's Abilify (aripiprazole), or mood stabilizers, such as Janssen Pharmaceutica's Topamax (topiramate). In addition, Janssen's Spravato (intranasal esketamine), which has been approved for treatment-resistant depression and for depressive systems in adults with major depressive disorder with suicidal thoughts or actions, targets the NMDA receptor and is expected to have a faster onset of therapeutic effect as compared to currently available therapies.

Current treatments for Parkinson's Disease ("PD") are intended to improve the symptoms of patients. The cornerstone of PD therapy is levodopa, as it is the most effective therapy for reducing symptoms of PD. There are other drug therapies in development that will target the disease, such as gene and stem cell therapy and A2A receptor agonists.

Further, despite the great need for an effective disease-modifying treatment for ALS and significant research efforts by the pharmaceutical industry to meet this need, there have been limited clinical successes and no curative therapies approved to date. In May 2022, the FDA approved an orally administered version of edaravone, which has been available since 2017 as an intravenous infusion for the treatment of ALS. In July 2022, the FDA accepted an NDA for tofersen, an investigational drug from Biogen Inc., for the treatment of superoxide dismutase 1 ALS. The NDA has been granted priority review with a Prescription Drug User Fee Act goal date of April 25, 2023. Additionally, in September 2022, the FDA approved AMX0035, now branded as Relyvrio, a drug from Amylyx Pharmaceuticals, Inc., for the treatment of ALS. AMX0035 previously received a conditional approval by Health Canada in June 2022.

We, or any future collaborators, may not be able to obtain orphan drug designation or orphan drug exclusivity for our product candidates.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. In the United States and Europe, obtaining orphan drug approval may allow us to obtain financial incentives, such as an extended period of exclusivity during which only we are allowed to market the orphan drug. While we have received orphan drug designation for SLS-005 in Sanfilippo Syndrome and in spinocerebellar ataxia type 3 and in oculopharyngeal muscular dystrophy and we plan to seek orphan drug designation from the FDA for SLS-008 for the treatment of a pediatric indication, we, or any future collaborators, may not be granted orphan drug designations for our product candidates in the U.S. or in other jurisdictions.

Even if we, or any future collaborators, obtain orphan drug designation for a product candidate, we, or they, may not be able to obtain orphan drug exclusivity for that product candidate. Generally, a product with orphan drug designation only becomes entitled to orphan drug exclusivity if it receives the first marketing approval for the indication for which it has such designation, in which case the FDA or the EMA will be precluded from approving another marketing application for the same drug for that indication for the applicable exclusivity period. The applicable exclusivity period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we, or any future collaborators, obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because FDA has taken the position that, under certain circumstances, another drug with the same active chemical and pharmacological characteristics, or moiety, can be approved for the same condition. Specifically, the FDA's regulations provide that it can approve another drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

The active ingredient of our lead product candidate, SLS-002, ketamine hydrochloride, is recognized as having the potential for abuse, misuse and diversion and, as a result, is and will be subject to extensive federal and state laws and regulations governing controlled substances and the entities involved in their research, manufacturing, sale and distribution, and possession. In addition, we anticipate that if we obtain marketing approval for SLS-002 it will be the subject of an FDA Risk Evaluation and Mitigation Strategy (REMS).

Ketamine is listed by the Drug Enforcement Administration ("DEA") as a Schedule III controlled substance under the Controlled Substances Act. The DEA classifies substances as Schedule I, II, III, IV or V controlled substances, with Schedule I controlled substances considered to present the highest risk of substance abuse and Schedule V controlled substances the lowest risk. Scheduled controlled substances are subject to DEA regulations relating to supply, procurement, manufacturing, storage, distribution and physician prescription procedures. In addition to federal scheduling, some drugs may be subject to state-level controlled substance laws and regulations and in some cases more broadly applicable or more extensive requirements than those determined by the DEA and FDA. Federal and state-level controlled substance laws impose a broad range of registration and licensure requirements along with requirements for systems and controls intended to provide security and reduce the risk of diversion and misuse, and to identify suspicious activities.

Compliance with these laws can be expensive and time consuming. Failure to follow these requirements can lead to significant civil and/or criminal penalties and possibly even lead to a revocation of a DEA registration and state-level licenses.

If SLS-002 receives marketing approval from the FDA or other regulatory authority, we may be required to implement REMS to address the potential for abuse and misuse of our product candidate. As a result, our product candidate may only be available through a restricted or limited distribution system to which only certain prescribing healthcare professionals may have access for their patients or healthcare professionals may be limited in their prescribing.

Furthermore, product candidates containing controlled substances may generate public controversy. As a result, these products may be at risk of having their sale and distribution and marketing approvals further restricted or in extreme cases withdrawn in the event that regulators were to assess that the benefits of a product no longer outweigh emerging risks. Political pressures or adverse publicity could lead to delays in, and increased expenses for, and limit or restrict, the commercialization of our product or product candidates.

We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates.

The process of manufacturing our product candidates is complex, highly regulated, and subject to several risks. For example, the process of manufacturing our product candidates is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing processes for any of our product candidates could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. In addition, the manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, public health crises, pandemics and epidemics, power failures and numerous other factors.

In addition, any adverse developments affecting manufacturing operations for our product candidates may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls or other interruptions in the supply of our product candidates. We also may need to take inventory write-offs and incur other charges and expenses for product candidates that fail to meet specifications, undertake costly remediation efforts or seek costlier manufacturing alternatives.

We rely completely on third parties to manufacture our preclinical and clinical drug supplies, and our business, financial condition and results of operations could be harmed if those third parties fail to provide us with sufficient quantities of drug product, or fail to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture our preclinical and clinical drug supplies for use in our clinical trials, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our product candidates, and there may be a need to identify alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and, if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete such clinical trial, any significant delay or discontinuity in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates, which could harm our business, financial condition and results of operations.

Product candidates that are considered combination products for FDA purposes, such as the SLS-002 drug-device combination product consisting of ketamine hydrocholoride and a USP aqueous spray solution in a bi-dose nasal delivery device, may face additional challenges, risks and delays in the product development and regulatory approval process.

SLS-002 is delivered by an intranasal delivery device and considered a drug-device combination product (the device having been developed by a third party is subject to a license agreement). When evaluating products that utilize a specific drug delivery system or device, the FDA will evaluate the characteristics of that delivery system and its functionality, as well as the potential for undesirable interactions between the drug and the delivery system, including the potential to negatively impact the safety or effectiveness of the drug. The FDA review process can be more complicated for combination products, and may result in delays, particularly if novel delivery systems are involved. Additionally, quality or design concerns with the delivery system could delay or prevent regulatory approval and commercialization of our product candidates.

We and our contract manufacturers are subject to significant regulation with respect to manufacturing our product candidates. The manufacturing facilities on which we rely may not continue to meet regulatory requirements.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of an NDA or marketing authorization application ("MAA") on a timely basis and must adhere to GLP and cGMP regulations enforced by the FDA, the EMA or comparable foreign authorities through their facilities inspection program. Some of our contract manufacturers may not have produced a commercially approved pharmaceutical product and therefore may not have obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or any of our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we plan to oversee the contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly or time consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business, financial condition and results of operations.

If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA, the EMA or comparable foreign authorities can impose regulatory sanctions including, among other things, refusal to approve a pending application for a product candidate, withdrawal of an approval or suspension of production. As a result, our business, financial condition and results of operations may be materially and adversely affected.

Additionally, if supply from one manufacturer is interrupted, an alternative manufacturer would need to be qualified through an NDA supplement or MAA variation, or equivalent foreign regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies or trials if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur higher costs and could cause the delay or termination of clinical trials, regulatory submissions, required approvals, or commercialization of our product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

Any collaboration arrangement that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our current and potential future product candidates.

We may seek collaboration arrangements with biopharmaceutical companies for the development or commercialization of our current and potential future product candidates. To the extent that we decide to enter into collaboration agreements, we will face significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, execute and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we choose to enter into such arrangements, and the terms of the arrangements may not be favorable to us. If and when we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations.

Disagreements between parties to a collaboration arrangement can lead to delays in developing or commercializing the applicable product candidate and can be difficult to resolve in a mutually beneficial manner. In some cases, collaborations with biopharmaceutical companies and other third parties are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect our business, financial condition and results of operations.

If we are unable to develop our own commercial organization or enter into agreements with third parties to sell and market our product candidates, we may be unable to generate significant revenues.

We do not have a sales and marketing organization, and we have no experience as a company in the sales, marketing and distribution of pharmaceutical products. If any of our product candidates are approved for commercialization, we may be required to develop our sales, marketing and distribution capabilities, or make arrangements with a third party to perform sales and marketing services. Developing a sales force for any resulting product or any product resulting from any of our other product candidates is expensive and time consuming and could delay any product launch. We may be unable to establish and manage an effective sales force in a timely or cost-effective manner, if at all, and any sales force we do establish may not be capable of generating sufficient demand for our product candidates. To the extent that we enter into arrangements with collaborators or other third parties to perform sales and marketing services, our product revenues are likely to be lower than if we marketed and sold our product candidates independently. If we are unable to establish adequate sales and marketing capabilities, independently or with others, we may not be able to generate significant revenues and may not become profitable.

The commercial success of our product candidates depends upon their market acceptance among physicians, patients, healthcare payors and the medical community.

Even if our product candidates obtain regulatory approval, our products, if any, may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the effectiveness of our approved product candidates as compared to currently available products;
- patient willingness to adopt our approved product candidates in place of current therapies;
- our ability to provide acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- restrictions on use in combination with other products;
- availability of alternative treatments;
- pricing and cost-effectiveness assuming either competitive or potential premium pricing requirements, based on the profile of our product candidates and target markets;

- effectiveness of us or our partners' sales and marketing strategy;
- our ability to obtain sufficient third-party coverage or reimbursement; and
- potential product liability claims.

In addition, the potential market opportunity for our product candidates is difficult to precisely estimate. Our estimates of the potential market opportunity for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research reports and other surveys. Independent sources have not verified all of our assumptions. If any of these assumptions proves to be inaccurate, then the actual market for our product candidates could be smaller than our estimates of the potential market opportunity. If the actual market for our product candidates is smaller than we expect, our product revenue may be limited, it may be harder than expected to raise funds and it may be more difficult for us to achieve or maintain profitability. If we fail to achieve market acceptance of our product candidates in the U.S. and abroad, our revenue will be limited and it will be more difficult to achieve profitability.

If we fail to obtain and sustain an adequate level of reimbursement for our potential products by third-party payors, potential future sales would be materially adversely affected.

There will be no viable commercial market for our product candidates, if approved, without reimbursement from third-party payors. Reimbursement policies may be affected by future healthcare reform measures. We cannot be certain that reimbursement will be available for our current product candidates or any other product candidate we may develop. Additionally, even if there is a viable commercial market, if the level of reimbursement is below our expectations, our anticipated revenue and gross margins will be adversely affected.

Third-party payors, such as government or private healthcare insurers, carefully review and increasingly question and challenge the coverage of and the prices charged for drugs. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan and other factors. Reimbursement rates may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. There is a current trend in the U.S. healthcare industry toward cost containment.

Large public and private payors, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payors, including Medicare, may question the coverage of, and challenge the prices charged for, medical products and services, and many third-party payors limit coverage of or reimbursement for newly approved healthcare products. In particular, third-party payors may limit the covered indications. Cost-control initiatives could decrease the price we might establish for products, which could result in product revenues being lower than anticipated. We believe our drugs will be priced significantly higher than existing generic drugs and consistent with current branded drugs. If we are unable to show a significant benefit relative to existing generic drugs, Medicare, Medicaid and private payors may not be willing to provide reimbursement for our drugs, which would significantly reduce the likelihood of our products gaining market acceptance.

We expect that private insurers will consider the efficacy, cost-effectiveness, safety and tolerability of our potential products in determining whether to approve reimbursement for such products and at what level. Obtaining these approvals can be a time consuming and expensive process. Our business, financial condition and results of operations would be materially adversely affected if we do not receive approval for reimbursement of our potential products from private insurers on a timely or satisfactory basis. Limitations on coverage could also be imposed at the local Medicare carrier level or by fiscal intermediaries. Medicare Part D, which provides a pharmacy benefit to Medicare patients as discussed below, does not require participating prescription drug plans to cover all drugs within a class of products. Our business, financial condition and results of operations could be materially adversely affected if Part D prescription drug plans were to limit access to, or deny or limit reimbursement of, our product candidates or other potential products.

Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis. In many countries, the product cannot be commercially launched until reimbursement is approved. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. The negotiation process in some countries can exceed 12 months. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products to other available therapies.

If the prices for our potential products are reduced or if governmental and other third-party payors do not provide adequate coverage and reimbursement of our drugs, our future revenue, cash flows and prospects for profitability will suffer.

Current and future legislation may increase the difficulty and cost of commercializing our product candidates and may affect the prices we may obtain if our product candidates are approved for commercialization.

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

In the U.S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") changed the way Medicare covers and pays for pharmaceutical products. Cost reduction initiatives and other provisions of this legislation could limit the coverage and reimbursement rate that we receive for any of our approved products. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively the "PPACA"), was enacted. The PPACA was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The PPACA increased manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate amount for both branded and generic drugs and revised the definition of "average manufacturer price", which may also increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The legislation also expanded Medicaid drug rebates and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the rebates due on those drugs. The Centers for Medicare & Medicaid Services, which administers the Medicaid Drug Rebate Program, also has proposed to expand Medicaid rebates to the utilization that occurs in the territories of the U.S., such as Puerto Rico and the Virgin Islands. Further, beginning in 2011, the PPACA imposed a significant annual fee on companies that manufacture or import branded prescription drug products and required manufacturers to provide a 50% discount off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the "donut hole." Legislative and regulatory proposals have been introduced at both the state and federal level to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products.

There have been public announcements by members of the U.S. Congress regarding plans to repeal and replace or amend and expand the PPACA and Medicare. For example, on December 22, 2017 the Tax Cuts and Jobs Act of 2017 was signed into law, which, among other things, eliminated the individual mandate requiring most Americans (other than those who qualify for a hardship exemption) to carry a minimum level of health coverage, effective January 1, 2019. We are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing approval testing and other requirements.

In addition to the PPACA, there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payers to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge for our current and future solutions or the amounts of reimbursement available for our current and future solutions from governmental agencies or third-party payers. While in general it is difficult to predict specifically what effects the PPACA or any future healthcare reform legislation or policies will have on our business, current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.

In Europe, the United Kingdom withdrew from the European Union on January 31, 2020 and began a transition period that ended on December 31, 2020. Although the ultimate effects of Brexit have yet to be seen, Brexit has created additional uncertainties that may ultimately result in new regulatory costs and challenges for companies and increased restrictions on imports and exports throughout Europe, which could adversely affect our ability to conduct and expand our operations in Europe and which may have an adverse effect on our business, financial condition and results of operations. Additionally, Brexit may increase the possibility that other countries may decide to leave the EU in the future.

In addition, on August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022, which, among other things, includes policies that are designed to have a direct impact on drug prices and reduce drug spending by the federal government, which shall take effect in 2023. Under the Inflation Reduction Act, Congress authorized Medicare beginning in 2026 to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars. This provision is limited in terms of the number of pharmaceuticals whose prices can be negotiated in any given year and it only applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years. Drugs and biologics that have been approved for a single rare disease or condition are categorically excluded from price negotiation. Further, the new legislation provides that if pharmaceutical companies raise prices in Medicare faster than the rate of inflation, they must pay rebates back to the government for the difference. The new law also caps Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at $2,000 a year.

Changes in government funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, properly administer drug innovation, or prevent our product candidates from being developed or commercialized, which could negatively impact our business, financial condition and results of operations.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including budget and funding levels, ability to hire and retain key personnel, 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 other agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

In December 2016, the 21st Century Cures Act was signed into law. This new legislation is designed to advance medical innovation and empower the FDA with the authority to directly hire positions related to drug and device development and review. However, government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies. These budgetary pressures may result in a reduced ability by the FDA to perform their respective roles; including the related impact to academic institutions and research laboratories whose funding is fully or partially dependent on both the level and timing of funding from government sources.

Disruptions at the FDA and other agencies may also slow the time necessary for our product candidates to be reviewed or approved by necessary government agencies, which could adversely affect our business, financial condition and results of operations.

We are subject to "fraud and abuse" and similar laws and regulations, and a failure to comply with such regulations or prevail in any litigation related to noncompliance could harm our business, financial condition and results of operations.

In the U.S., we are subject to various federal and state healthcare "fraud and abuse" laws, including anti-kickback laws, false claims laws and other laws intended, among other things, to reduce fraud and abuse in federal and state healthcare programs. The federal Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer, or a party acting on its behalf, to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce the referral of business, including the purchase, order or prescription of a particular drug, or other good or service for which payment in whole or in part may be made under a federal healthcare program, such as Medicare or Medicaid. Although we seek to structure our business arrangements in compliance with all applicable requirements, these laws are broadly written, and it is often difficult to determine precisely how the law will be applied in specific circumstances. Accordingly, it is possible that our practices may be challenged under the federal Anti-Kickback Statute.

The federal False Claims Act prohibits anyone from, among other things, knowingly presenting or causing to be presented for payment to the government, including the federal healthcare programs, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services that were not provided as claimed, or claims for medically unnecessary items or services. Under the Health Insurance Portability and Accountability Act of 1996, we are prohibited from knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services to obtain money or property of any healthcare benefit program. Violations of fraud and abuse laws may be punishable by criminal or civil sanctions, including penalties, fines or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the government under the federal False Claims Act as well as under the false claims laws of several states.

Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payors. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement, we could be subject to penalties.

Neither the government nor the courts have provided definitive guidance on the application of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. If we are found in violation of one of these laws, we could be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from governmental funded federal or state healthcare programs and the curtailment or restructuring of our operations. If this occurs, our business, financial condition and results of operations may be materially adversely affected.

If we face allegations of noncompliance with the law and encounter sanctions, our reputation, revenues and liquidity may suffer, and any of our product candidates that are ultimately approved for commercialization could be subject to restrictions or withdrawal from the market.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to generate revenues from any of our product candidates that are ultimately approved for commercialization. If regulatory sanctions are applied or if regulatory approval is withdrawn, our business, financial condition and results of operations will be adversely affected. Additionally, if we are unable to generate revenues from product sales, our potential for achieving profitability will be diminished and our need to raise capital to fund our operations will increase.

If we fail to retain current members of our senior management and scientific personnel, or to attract and keep additional key personnel, we may be unable to successfully develop or commercialize our product candidates.

Our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. As of February 24, 2023, we have 16 employees. Our organization will rely primarily on outsourcing research, development and clinical trial activities, and manufacturing operations, as well as other functions critical to our business. We believe this approach enhances our ability to focus on our core product opportunities, allocate resources efficiently to different projects and allocate internal resources more effectively. We have filled several key open positions and are currently recruiting for a few remaining positions. However, competition for qualified personnel is intense. In addition, regulation or legislation impacting the workforce, such as the proposed rule published by the Federal Trade Commission which would, if issued, generally prevent employers from entering into non-compete agreements with employees and require employers to rescind existing non-compete agreements, may lead to increased uncertainty in hiring and competition for talent. We may not be successful in attracting qualified personnel to fulfill our current or future needs and there is no guarantee that any of these individuals will join us on a full-time employment basis, or at all. In the event we are unable to fill critical open employment positions, we may need to delay our operational activities and goals, including the development of our product candidates, and may have difficulty in meeting our obligations as a public company. In addition, we may experience employee turnover as a result of the ongoing "great resignation" occurring throughout the U.S. economy, which has impacted job market dynamics. New hires require training and take time before they achieve full productivity. New employees may not become as productive as we expect, and we may be unable to hire or retain sufficient numbers of qualified individuals. In the event we are unable to fill critical open employment positions, we may need to delay our operational activities and goals, including the development of our product candidates, and may have difficulty in meeting our obligations as a public company. We do not maintain "key person" insurance on any of our employees.

In addition, competitors and others are likely in the future to attempt to recruit our employees. The loss of the services of any of our key personnel, the inability to attract or retain highly qualified personnel in the future or delays in hiring such personnel, particularly senior management and other technical personnel, could materially and adversely affect our business, financial condition and results of operations. Moreover, regulation or legislation impacting the workforce, such as the proposed rule published by the Federal Trade Commission which would, if issued, generally prevent employers from entering into non-compete with employees and require employers to rescind existing non-competes, may lead to increased uncertainty in hiring and competition for talent. In addition, the replacement of key personnel likely would involve significant time and costs, and may significantly delay or prevent the achievement of our business objectives.

From time to time, our management seeks the advice and guidance of certain scientific advisors and consultants regarding clinical and regulatory development programs and other customary matters. These scientific advisors and consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our scientific advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with us.

We will need to increase the size of our organization and may not successfully manage our growth.

We are a clinical-stage biopharmaceutical company with a small number of planned employees, and our management system currently in place is not likely to be adequate to support our future growth plans. Our ability to grow and to manage our growth effectively will require us to hire, train, retain, manage and motivate additional employees and to implement and improve our operational, financial and management systems. These demands also may require the hiring of additional senior management personnel or the development of additional expertise by our senior management personnel. Hiring a significant number of additional employees, particularly those at the management level, would increase our expenses significantly. Moreover, if we fail to expand and enhance our operational, financial and management systems in conjunction with our potential future growth, it could have a material adverse effect on our business, financial condition and results of operations.

Our management's limited public company experience could put us at greater risk of incurring fines or regulatory actions for failure to comply with federal securities laws and could put us at a competitive disadvantage, and could require our management to devote additional time and resources to ensure compliance with applicable corporate governance requirements.

Our executive officers have limited prior experience as executive officers in managing and operating a public company, which could have an adverse effect on their ability to quickly respond to problems or adequately address issues and matters applicable to public companies. Any failure to comply with federal securities laws, rules or regulations could subject us to fines or regulatory actions, which may materially adversely affect our business, financial condition and results of operations. Further, since our executive officers have limited prior experience as executive officers managing and operating a public company, we may need to dedicate additional time and resources to comply with legally mandated corporate governance policies relative to our competitors whose management teams have more public company experience.

We are exposed to product liability, non-clinical and clinical liability risks which could place a substantial financial burden upon us, should lawsuits be filed against us.

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical formulations and products. In addition, the use in our clinical trials of pharmaceutical products and the subsequent sale of these products by us or our potential collaborators may cause us to bear a portion of or all product liability risks. A successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

We currently carry product liability insurance for our clinical development activities. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Our research and development activities involve the use of hazardous materials, which subject us to regulation, related costs and delays and potential liabilities.

Our research and development activities involve the controlled use of hazardous materials and chemicals, and we will need to develop additional safety procedures for the handling and disposing of hazardous materials. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate any of these laws or regulations.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our drug development and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of drug development or clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs and the development of our product candidates could be delayed.

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

We are exposed to the risk of employee or consultant fraud or other misconduct. Misconduct by our employees or consultants could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commissions, customer incentive programs and other business arrangements. Employee and consultant misconduct also could involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter such misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material adverse effect on our business, financial condition and results of operations, and result in the imposition of significant fines or other sanctions against us.

Business disruptions such as natural disasters could seriously harm our future revenues and financial condition and increase our costs and expenses.

We and our suppliers may experience a disruption in our and their business as a result of natural disasters. A significant natural or man-made disaster, such as an earthquake, power outages, hurricane, flood or fire, droughts and other extreme weather events and changing weather patterns, which are increasing in frequency due to the impacts of climate change, could severely damage or destroy our headquarters or facilities or the facilities of our manufacturers or suppliers, which could have a material and adverse effect on our business, financial condition and results of operations. In addition, terrorist acts or acts of war targeted at the U.S., and specifically the greater New York, New York region, could cause damage or disruption to us, our employees, facilities, partners and suppliers, which could have a material adverse effect on our business, financial condition and results of operations.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of products, product candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our business, financial condition and results of operations. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for any of these transactions;
- higher-than-expected transaction and integration costs;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses or product lines with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses or product lines due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks, and could have a material adverse effect on our business, financial condition and results of operations.

Compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the EU General Data Protection Regulation (the "GDPR"), which took effect across all member states of the European Economic Area (the "EEA") in May 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. In addition, the GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States and, as a result, increases the scrutiny that clinical trial sites located in the EEA should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal information and/or impose substantial fines for violations of the GDPR, which can be up to 4% of global revenues or €20 million, whichever is greater, and it also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that EU member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

Similar actions are either in place or under way in the United States. There are a broad variety of data protection laws that are applicable to our activities, and a wide range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission and state Attorneys General all are aggressive in reviewing privacy and data security protections for consumers. New laws also are being considered at both the state and federal levels. For example, the California Consumer Privacy Act (the "CCPA"), which went into effect on January 1, 2020, and was amended by the California Privacy Rights Act (the "CPRA"), effective January 1, 2023, secure new privacy rights for consumers and impose new obligations on us. Many other states have implemented or are considering similar legislation which will change the privacy law landscape in the United States. For example, Virginia, Colorado, Utah and Connecticut have all adopted privacy laws, which take effect in 2023. A broad range of legislative measures also have been introduced at the federal level. Accordingly, failure to comply with federal and state laws (both those currently in effect and future legislation) regarding privacy and security of personal information could expose us to fines and penalties under such laws. There also is the threat of consumer class actions related to these laws and the overall protection of personal data.

Given the breadth and depth of changes in data protection obligations, preparing for and complying with these requirements is rigorous and time intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data collected in the European Union. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition or results of operations. Similarly, failure to comply with federal and state laws regarding privacy and security of personal information could expose us to fines and penalties under such laws. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. If we fail to comply with these laws, we could be subject to civil or criminal liabilities, other remedial measures and legal expenses, be precluded from developing, manufacturing and selling certain products outside the United States or be required to develop and implement costly compliance programs, which could adversely affect our business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the U.S. Foreign Corrupt Practices Act (the "FCPA"), the U.K. Bribery Act 2010 (the "Bribery Act") and other anti-corruption laws that apply in countries where we do business and may do business in the future. The FCPA, the Bribery Act and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. Compliance with the FCPA, in particular, is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

We may in the future operate in jurisdictions that pose a high risk of potential FCPA or Bribery Act violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA, the Bribery Act or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. If we expand our operations outside of the United States, we will need to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United States, the United Kingdom and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations (collectively referred to as "Trade Control Laws"). In addition, various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA, the Bribery Act or other legal requirements, including Trade Control Laws. If we are not in compliance with the FCPA, the Bribery Act and other anti-corruption laws or Trade Control Laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. The Securities and Exchange Commission also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Any investigation of any potential violations of the FCPA, the Bribery Act, other anti-corruption laws or Trade Control Laws by U.S., United Kingdom or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

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

In some countries, particularly 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 European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we, or our future collaborators, may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates 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 the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

Investors' expectations of our performance relating to environmental, social and governance factors may impose additional costs and expose us to new risks.

There is an increasing focus from certain investors, employees, regulators and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance, or ESG, factors. Some investors and investor advocacy groups may use these factors to guide investment strategies and, in some cases, investors may choose not to invest in our company if they believe our policies relating to corporate responsibility are inadequate. Third-party providers of corporate responsibility ratings and reports on companies have increased to meet growing investor demand for measurement of corporate responsibility performance, and a variety of organizations currently measure the performance of companies on such ESG topics, and the results of these assessments are widely publicized. Investors, particularly institutional investors, use these ratings to benchmark companies against their peers and if we are perceived as lagging with respect to ESG initiatives, certain investors may engage with us to improve ESG disclosures or performance and may also make voting decisions, or take other actions, to hold us and our board of directors accountable. In addition, the criteria by which our corporate responsibility practices are assessed may change, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. If we elect not to or are unable to satisfy such new criteria, investors may conclude that our policies with respect to corporate responsibility are inadequate.

We may face reputational damage in the event our corporate responsibility initiatives or objectives do not meet the standards set by our investors, stockholders, lawmakers, listing exchanges or other constituencies, or if we are unable to achieve an acceptable ESG or sustainability rating from third-party rating services. A low ESG or sustainability rating by a third-party rating service could also result in the exclusion of our common stock from consideration by certain investors who may elect to invest with our competition instead. Ongoing focus on corporate responsibility matters by investors and other parties as described above may impose additional costs or expose us to new risks. Any failure or perceived failure by us in this regard could have a material adverse effect on our reputation and on our business, share price, financial condition, or results of operations, including the sustainability of our business over time.

In addition, the SEC has announced proposed rules that, among other matters, will establish a framework for reporting of climate-related risks. To the extent the proposed rules impose additional reporting obligations, we could face increased costs. Separately, the SEC has also announced that it is scrutinizing existing climate-change related disclosures in public filings, increasing the potential for enforcement if the SEC were to allege our existing climate disclosures are misleading or deficient.

Risks Related to Our Intellectual Property

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

Because several of our programs require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to maintain and exploit these proprietary rights. In addition, we may need to acquire or in-license additional intellectual property in the future. We may be unable to acquire or in-license any compositions, methods of use, processes or other intellectual property rights from third parties that we identify as necessary for our product candidates. We face competition with regard to acquiring and in-licensing third-party intellectual property rights, including from a number of more established companies. These established companies may have a competitive advantage over us due to their size, cash 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 intellectual property rights to us. We also may be unable to acquire or in-license third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

We may enter into collaboration agreements with U.S. and foreign academic institutions to accelerate development of our current or future preclinical product candidates. Typically, these agreements include an option for the company to negotiate a license to the institution's intellectual property rights resulting from the collaboration. Even with such an 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 license rights from a collaborating institution, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our desired program.

If we are unable to successfully obtain required third-party intellectual property rights or maintain our existing intellectual property rights, including if our patent applications do not result in the issuance of patents, we may need to abandon development of the related program and our business, financial condition and results of operations could be materially and adversely affected.

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

Our license agreement with Ligand Pharmaceuticals Incorporated, Neurogen Corporation and CyDex Pharmaceuticals, Inc. (the "Ligand License Agreement"), our license agreement with the Regents of the University of California (the "UC Regents License Agreement"), our license agreement with Duke University (the "Duke License Agreement") and our license agreement with iX Biopharma Ltd. (the "iX License Agreement", together with the Ligand License Agreement, the UC Regents License Agreement, and the Duke License Agreement, the "License Agreements") are important to our business and we expect to enter into additional license agreements in the future. The License Agreements impose, and we expect that future license agreements will impose, various milestone payments, royalties and other obligations on us. If we fail to comply with our obligations under these agreements, or if we file for bankruptcy, we may be required to make certain payments to the licensor, we may lose the exclusivity of our license, or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. Additionally, the milestone and other payments associated with these licenses could materially and adversely affect our business, financial condition and results of operations.

Pursuant to the terms of the Ligand License Agreement, the licensors each have the right to terminate the Ligand License Agreement with respect to the programs licensed by such licensor under certain circumstances, including, but not limited to: (i) if we do not pay an amount that is not disputed in good faith, (ii) if we willfully breach the Ligand License Agreement in a manner for which legal remedies would not be expected to make such licensor whole, or (iii) if we file or have filed against us a petition in bankruptcy or make an assignment for the benefit of creditors. In the event the Ligand License Agreement is terminated by a licensor, all licenses granted to us by such licensor will terminate immediately. Further, pursuant to the terms of the UC Regents License Agreement, the licensor has the right to terminate the UC Regents License Agreement or reduce our license to a nonexclusive license if we fail to achieve certain milestones within a specified timeframe. Similarly, pursuant to the terms of the Duke License Agreement and the iX License Agreement, each licensor has the right to terminate the Duke License Agreement or the iX License Agreement, as applicable, if we fail to achieve certain milestones within a specified timeframe.

In some cases, patent prosecution of our licensed technology may be controlled solely by the licensor. If our licensor fails to obtain and maintain patent or other protection for the proprietary intellectual property we in-license, then we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, we may control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise regarding intellectual property subject to a licensing agreement, including, but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by us, our licensors and our collaborators; and
- the priority of invention of patented technology.

If disputes over intellectual property and other rights that we have in-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 any such obligations to our licensor, such licensor may terminate its licenses to us, in which case we would not be able to market products covered by these licenses. The loss of our licenses would have a material adverse effect on our business.

We are required to make certain cash payments and may be required to pay milestones and royalties pursuant to certain commercial agreements, which could adversely affect the overall profitability for us of any products that we may seek to commercialize.

Under the terms of the Ligand License Agreement, we may be obligated to pay the licensor under the Ligand License Agreement up to an aggregate of approximately $126.7 million in development, regulatory and sales milestones. Similarly, under the terms of the iX License Agreement, we may be obligated to pay the licensor under the iX License Agreement up to an aggregate of approximately $239 million in development, regulatory and sales milestones. We will also be required to pay royalties on future worldwide net product sales. We will also be required to pay up to an aggregate of approximately $17 million in development and regulatory milestones and royalties on any net sales of SLS-005 pursuant to our asset purchase agreement with Bioblast Pharma Ltd. These cash, milestone and royalty payments could adversely affect the overall profitability for us of any products that we may seek to commercialize.

We may not be able to protect our proprietary or licensed technology in the marketplace.

We depend on our ability to protect our proprietary or licensed technology. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our success depends in large part on our ability and any licensor's or licensee's ability to obtain and maintain patent protection in the U.S. and other countries with respect to our proprietary or licensed technology and products. We currently in-license some of our intellectual property rights to develop our product candidates and may in-license additional intellectual property rights in the future. We cannot be certain that patent enforcement activities by our current or future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. We also cannot be certain that our current or future licensors will allocate sufficient resources or prioritize their or our enforcement of such patents. Even if we are not a party to these legal actions, an adverse outcome could prevent us from continuing to license intellectual property that we may need to operate our business, which would have a material adverse effect on our business, financial condition and results of operations.

Although we believe we will be able to obtain, through prosecution of patent applications covering our owned technology and technology licensed from others, adequate patent protection for our proprietary drug technology, including those related to our in-licensed intellectual property, if we are compelled to spend significant time and money protecting or enforcing our licensed patents and future patents we may own, designing around patents held by others or licensing or acquiring, potentially for large fees, patents or other proprietary rights held by others, our business, financial condition and results of operations may be materially and adversely affected. If we are unable to effectively protect the intellectual property that we own or in-license, other companies may be able to offer the same or similar products for sale, which could materially adversely affect our business, financial condition and results of operations. The patents of others from whom we may license technology, and any future patents we may own, may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing the same or similar products or limit the length of term of patent protection that we may have for our products.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or patent applications will be due to be paid to the U.S. Patent and Trademark Office ("USPTO") and various governmental patent agencies outside of the U.S. in several stages over the lifetime of the applicable patent and/or patent application. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. 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. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If this occurs with respect to our in-licensed patents or patent applications we may file in the future, our competitors might be able to use our technologies, which would have a material adverse effect on our business, financial condition and results of operations.

The patent positions of pharmaceutical products are often complex and uncertain. The breadth of claims allowed in pharmaceutical patents in the U.S. and many jurisdictions outside of the U.S. is not consistent. For example, in many jurisdictions, the support standards for pharmaceutical patents are becoming increasingly strict. Some countries prohibit method of treatment claims in patents. Changes in either the patent laws or interpretations of patent laws in the U.S. and other countries may diminish the value of our licensed or owned intellectual property or create uncertainty. In addition, publication of information related to our current product candidates and potential products may prevent us from obtaining or enforcing patents relating to these product candidates and potential products, including without limitation composition-of-matter patents, which are generally believed to offer the strongest patent protection.

Patents that we currently license and patents that we may own or license in the future do not necessarily ensure the protection of our licensed or owned intellectual property for a number of reasons, including, without limitation, the following:

- the patents may not be broad or strong enough to prevent competition from other products that are identical or similar to our product candidates;

- there can be no assurance that the term of a patent can be extended under the provisions of patent term extensions afforded by U.S. law or similar provisions in foreign countries, where available;
- the issued patents and patents that we may obtain or license in the future may not prevent generic entry into the market for our product candidates;
- we, or third parties from whom we in-license or may license patents, may be required to disclaim part of the term of one or more patents;
- there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim;
- there may be prior art of which we are aware, which we do not believe affects the validity or enforceability of a patent claim, but which, nonetheless, ultimately may be found to affect the validity or enforceability of a patent claim;
- there may be other patents issued to others that will affect our freedom to operate;
- if the patents are challenged, a court could determine that they are invalid or unenforceable;
- there might be a significant change in the law that governs patentability, validity and infringement of our licensed patents or any future patents we may own that adversely affects the scope of our patent rights;
- a court could determine that a competitor's technology or product does not infringe our licensed patents or any future patents we may own; and
- the patents could irretrievably lapse due to failure to pay fees or otherwise comply with regulations or could be subject to compulsory licensing.

If we encounter delays in our development or clinical trials, the period of time during which we could market our potential products under patent protection would be reduced.

Our competitors may be able to circumvent our licensed patents or future patents we may own by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may seek to market generic versions of any approved products by submitting abbreviated new drug applications to the FDA in which our competitors claim that our licensed patents or any future patents we may own are invalid, unenforceable or not infringed. Alternatively, our competitors may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend or assert our licensed patents or any future patents we may own, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our licensed patents or any future patents we may own invalid or unenforceable. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Even if we own or in-license valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

The issuance of a patent is not conclusive as to its inventorship, scope, ownership, priority, validity or enforceability. In this regard, third parties may challenge our licensed patents or any future patents we may own in the courts or patent offices in the U.S. and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit 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 potential products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized.

We may infringe the intellectual property rights of others, which may prevent or delay our drug development efforts and prevent us from commercializing or increase the costs of commercializing our products.

Our commercial success depends significantly on our ability to operate without infringing the patents and other intellectual property rights of third parties. For example, there could be issued patents of which we are not aware that our current or potential future product candidates infringe. There also could be patents that we believe we do not infringe, but that we may ultimately be found to infringe.

Moreover, patent applications are in some cases maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications were filed. Because patents can take many years to issue, there may be currently pending applications of which we are unaware that may later result in issued patents that our product candidates or potential products infringe. For example, pending applications may exist that claim or can be amended to claim subject matter that our product candidates or potential products infringe. Competitors may file continuing patent applications claiming priority to already issued patents in the form of continuation, divisional, or continuation-in-part applications, in order to maintain the pendency of a patent family and attempt to cover our product candidates.

Third parties may assert that we are employing their proprietary technology without authorization and may sue us for patent or other intellectual property infringement. These lawsuits are costly and could adversely affect our business, financial condition and results of operations and divert the attention of managerial and scientific personnel. If we are sued for patent infringement, we would need to demonstrate that our product candidates, potential products or methods either do not infringe the claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the U.S., proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. If a court holds that any third-party patents are valid, enforceable and cover our products or their use, the holders of any of these patents may be able to block our ability to commercialize our products unless we acquire or obtain a license under the applicable patents or until the patents expire.

We may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost or on reasonable terms. Any inability to secure licenses or alternative technology could result in delays in the introduction of our products or lead to prohibition of the manufacture or sale of products by us. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially and adversely affect our business, financial condition and results of operations. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar material and adverse effect on our business, financial condition and results of operations. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Any claims or lawsuits relating to infringement of intellectual property rights brought by or against us will be costly and time consuming and may adversely affect our business, financial condition and results of operations.

We may be required to initiate litigation to enforce or defend our licensed and owned intellectual property. Lawsuits to protect our intellectual property rights can be very time consuming and costly. There is a substantial amount of litigation involving patent and other intellectual property rights in the biopharmaceutical industry generally. Such litigation or proceedings could substantially increase our operating expenses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are resolved. Further, any claims we assert against a perceived infringer could provoke these parties to assert counterclaims against us alleging that we have infringed their patents. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

In addition, our licensed patents and patent applications, and patents and patent applications that we may apply for, own or license in the future, could face other challenges, such as interference proceedings, opposition proceedings, re-examination proceedings and other forms of post-grant review. Any of these challenges, if successful, could result in the invalidation of, or in a narrowing of the scope of, any of our licensed patents and patent applications and patents and patent applications that we may apply for, own or license in the future subject to challenge. Any of these challenges, regardless of their success, would likely be time consuming and expensive to defend and resolve and would divert our management and scientific personnel's time and attention.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

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 costly, time-consuming and inherently uncertain. For example, the U.S. previously enacted and is currently implementing wide-ranging patent reform legislation. Specifically, on September 16, 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act") was signed into law and included a number of significant changes to U.S. patent law, and many of the provisions became effective in March 2013. However, it may take the courts years to interpret the provisions of the Leahy-Smith Act, and the implementation of the statute could increase the uncertainties and costs surrounding the prosecution of our licensed and future patent applications and the enforcement or defense of our licensed and future patents, all of which could have a material adverse effect on our business, financial condition and results of operations.

In addition, 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. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we might obtain in the future.

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

Filing, prosecuting and defending patents on product candidates throughout the world would be prohibitively expensive. Competitors may use our licensed and owned technologies in jurisdictions where we have not licensed or obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain or license patent protection, but where patent enforcement is not as strong as that in the U.S. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our licensed patents and future patents we may own, or marketing of competing products in violation of our proprietary rights generally. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our licensed and owned intellectual property both in the U.S. and abroad. For example, China currently affords less protection to a company's intellectual property than some other jurisdictions. As such, the lack of strong patent and other intellectual property protection in China may significantly increase our vulnerability regarding unauthorized disclosure or use of our intellectual property and undermine our competitive position. Proceedings to enforce our future patent rights, if any, in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

In order to protect our proprietary and licensed technology and processes, we rely in part on confidentiality agreements with our corporate partners, employees, consultants, manufacturers, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of our confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

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

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest, and it may be difficult and costly to register, maintain and/or protect our rights to these trademarks and trade names in jurisdictions in and outside of the United States. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

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

We expect to employ individuals who were previously employed at other biopharmaceutical companies. Although we have no knowledge of any such claims against us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. To date, none of our employees have been subject to such claims.

We may be subject to claims challenging the inventorship of our licensed patents, any future patents we may own and other intellectual property.

Although we are not currently experiencing any claims challenging the inventorship of our licensed patents or our licensed or owned intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our licensed patents or other licensed or owned intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arising from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business, financial condition and results of operations. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

If we do not obtain additional protection under the Hatch-Waxman Amendments and similar foreign legislation extending the terms of our licensed patents and any future patents we may own, our business, financial condition and results of operations may be materially and adversely affected.

Depending upon the timing, duration and specifics of FDA regulatory approval for our product candidates, one or more of our licensed U.S. patents or future U.S. patents that we may license or own may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during drug development and the FDA regulatory review process. This period is generally one-half the time between the effective date of an investigational new drug application ("IND") (falling after issuance of the patent), and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Patent term restorations, however, cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval by the FDA.

The application for patent term extension is subject to approval by the USPTO, in conjunction with the FDA. It takes at least six months to obtain approval of the application for patent term extension. We may not be granted an extension because of, for example, 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 restoration or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain earlier approval of competing products, and our ability to generate revenues could be materially adversely affected.

Risks Related to Owning Our Common Stock

The market price of our common stock has been and will likely continue to be volatile.

The trading price of our common stock has been and is likely to continue to be volatile. For example, in 2022 our closing stock price ranged from $0.51 to $1.71 per share. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- results from, and any delays in, planned clinical trials for our product candidates, or any other future product candidates, and the results of trials of competitors or those of other companies in our market sector;
- any delay in filing an NDA for any of our product candidates and any adverse development or perceived adverse development with respect to the FDA's review of that NDA;
- significant lawsuits, including patent or stockholder litigation;
- inability to obtain additional funding;
- failure to successfully develop and commercialize our product candidates;
- changes in laws or regulations applicable to our product candidates;
- inability to obtain adequate product supply for our product candidates, or the inability to do so at acceptable prices;
- unanticipated serious safety concerns related to any of our product candidates;
- adverse regulatory decisions;
- introduction of new products or technologies by our competitors;
- failure to meet or exceed drug development or financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- the perception of the biopharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our licensed and owned technologies;
- additions or departures of key scientific or management personnel;
- changes in the market valuations of similar companies;
- general economic and market conditions and overall fluctuations in the U.S. equity market, including any potential recession or economic downturn;
- public health crises, pandemics and epidemics, such as the COVID-19 pandemic;
- sales of our common stock by us or our stockholders in the future; and
- the trading volume of our common stock.

In addition, the stock market in general, and small biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. Further, a decline in the financial markets and related factors beyond our control may cause our stock price to decline rapidly and unexpectedly.

If we fail to comply with the continued listing requirements of the Nasdaq Capital Market, 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.

We must continue to satisfy the Nasdaq Capital Market's continued listing requirements, including, among other things, a minimum closing bid price requirement of $1.00 per share for 30 consecutive business days. If a company fails for 30 consecutive business days to meet the $1.00 minimum closing bid price requirement, The Nasdaq Stock Market LLC ("Nasdaq") will send a deficiency notice to the company, advising that it has been afforded a "compliance period" of 180 calendar days to regain compliance with the applicable requirements.

A delisting of our common stock from the Nasdaq Capital Market 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 and employees.

On April 22, 2022, we received written notice from Nasdaq indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided an initial period of 180 calendar days, or until October 19, 2022, to regain compliance. On September 1, 2022, we received a letter from Nasdaq notifying us that we regained full compliance with Nasdaq Listing Rule 5550(a)(2) after the closing bid price of our common stock had been at $1.00 per share or greater for ten consecutive business days, from August 18, 2022 through August 31, 2022.

On November 21, 2022, we received an additional written notice from Nasdaq indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided an initial period of 180 calendar days, or until May 22, 2023, to regain compliance. The Nasdaq staff will provide written confirmation that we have achieved compliance with Rule 5550(a)(2) if at any time before May 22, 2023, the bid price of our common stock closes at $1.00 per share or more for a minimum of ten consecutive business days. We intend to monitor the bid price of our common stock and consider available options if our common stock does not trade at a level likely to result in our regaining compliance with The Nasdaq Capital Market's minimum bid price rule by May 22, 2023, which may include, among other options, effectuating a reverse stock split. There is no guarantee that we will regain compliance by May 22, 2023. If we do not regain compliance with Rule 5550(a)(2) by May 22, 2023, we may be afforded a second 180 calendar day period to regain compliance. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, except for the minimum bid price requirement. In addition, we would be required to notify Nasdaq of our intent to cure the deficiency during the second compliance period, which may include, if necessary, implementing a reverse stock split.

In addition, we have previously received similar notices from Nasdaq that our bid price of our common stock had closed below the minimum $1.00 per share requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2). Even though we previously regained compliance with the Nasdaq Capital Market's minimum market value of listed securities requirement and minimum closing bid price requirement, there is no guarantee that we will remain in compliance with such listing requirements or other listing requirements in the future. Any failure to maintain compliance with continued listing requirements of the Nasdaq Capital Market could result in delisting of our common stock from the Nasdaq Capital Market and negatively impact our company and holders of our common stock, including by reducing the willingness of investors to hold our common stock because of the resulting decreased price, liquidity and trading of our common stock, limited availability of price quotations and reduced news and analyst coverage. Delisting may adversely impact the perception of our financial condition, cause reputational harm with investors, our employees and parties conducting business with us and limit our access to debt and equity financing.

We will incur significant costs as a result of operating as a public company and our management will be required to devote substantial time to new compliance initiatives.

The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (the "Dodd-Frank Act") as well as rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact (in ways we cannot currently anticipate) the manner in which we operate our business. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such insurance coverage.

As a publicly traded company, we will incur legal, accounting and other expenses associated with the SEC reporting requirements applicable to a company whose securities are registered under the Exchange Act, as well as corporate governance requirements, including those under the Sarbanes-Oxley Act, the Dodd-Frank Act and other rules implemented by the SEC and Nasdaq. The expenses incurred by public companies generally to meet SEC reporting, finance and accounting and corporate governance requirements have been increasing in recent years as a result of changes in rules and regulations and the adoption of new rules and regulations applicable to public companies.

Sales of a substantial number of shares of our common stock in the public market by our existing stockholders, future issuances of our common stock or rights to purchase our common stock, could cause our stock price to fall.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. As of December 31, 2022, we have outstanding warrants to purchase an aggregate of approximately 2.5 million shares of our common stock, which, if exercised, would further increase the number of shares of our common stock outstanding and the number of shares eligible for resale in the public market. As of December 31, 2022, 18,873,072 shares of our common stock were reserved for issuance under our equity incentive plans, of which 10,399,170 shares of our common stock were subject to options outstanding at such date at a weighted-average exercise price of $2.26 per share, 5,418,648 shares of our common stock were reserved for future issuance pursuant to our Amended and Restated 2012 Stock Long Term Incentive Plan, 646,465 shares of our common stock were reserved for future issuance pursuant to our 2019 Inducement Plan and 2,408,789 shares of our common stock were reserved for issuance pursuant to our 2020 Employee Stock Purchase Plan. To the extent outstanding options are exercised, our existing stockholders may incur dilution. Furthermore, from time to time and before the maturity date of the Convertible Promissory Note, Lind currently has the option to convert any portion of the then-outstanding principal amount of the Convertible Promissory Note into shares of our common stock at a price per share of $6.00, subject to adjustment for stock splits, reverse stock splits, stock dividends and similar transactions. We may also elect to make amortization and interest payments on the Convertible Promissory Note in the form of shares of our common stock, with the number of shares issuable calculated based on ninety percent (90%) of the average of the five (5) lowest daily volume weighted average price of shares of our common stock during the twenty (20) trading days ending on the last trading day prior to such payment date. Any issuances of shares of our common stock pursuant to the Convertible Promissory Note will result in dilution to our then-existing stockholders and increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market could depress the market price of our common stock.

The Financing Warrants contain price-based adjustment provisions which, if triggered, may cause substantial additional dilution to our stockholders.

On October 16, 2018, we entered into a Securities Purchase Agreement with the investors listed on the Schedule of Buyers attached thereto, as amended, pursuant to which, among other things, we issued warrants to purchase shares of our common stock (the "Financing Warrants").

The outstanding Financing Warrants contain price-based adjustment provisions, pursuant to which the exercise price of the Financing Warrants may be adjusted downward in the event of certain dilutive issuances by us.

If the Financing Warrants are exercised, additional shares of our common stock will be issued, which will result in dilution to our then-existing stockholders and increase the number of shares eligible for resale in the public market. As of December 31, 2022, the Financing Warrants were exercisable for approximately 0.3 million shares of our common stock at an exercise price of $0.2957 per share of common stock. Sales of substantial numbers of such shares in the public market could depress the market price of our common stock.

Anti-takeover provisions in our governing documents and under Nevada law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our management.

Provisions in our articles of incorporation and bylaws may delay or prevent an acquisition or a change in management. These provisions include a classified board of directors and the ability of the board of directors to issue preferred stock without stockholder approval. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

Certain provisions of Nevada corporate law deter hostile takeovers. Specifically, Nevada Revised Statutes ("NRS") 78.411 through 78.444 prohibit a publicly held Nevada corporation from engaging in a "combination" with an "interested stockholder" for a period of two years following the date the person first became an interested stockholder, unless (with certain exceptions) the "combination" or the transaction by which the person became an interested stockholder is approved in a prescribed manner. Generally, a "combination" includes a merger, asset or stock sale, or certain other transactions resulting in a financial benefit to the interested stockholder. Generally, an "interested stockholder" is a person who, together with affiliates and associates, beneficially owns or within two years prior to becoming an "interested stockholder" did own, 10% or more of a corporation's voting power. While these statutes permit a corporation to opt out of these protective provisions in its articles of incorporation, our articles of incorporation do not include any such opt-out provision.

Nevada's "acquisition of controlling interest" statutes, NRS 78.378 through 78.3793, contain provisions governing the acquisition of a controlling interest in certain Nevada corporations. These "control share" laws provide generally that any person that acquires a "controlling interest" in certain Nevada corporations may be denied voting rights, unless a majority of the disinterested stockholders of the corporation elects to restore such voting rights. These statutes provide that a person acquires a "controlling interest" whenever a person acquires shares of a subject corporation that, but for the application of these provisions of the NRS, would enable that person to exercise (1) one-fifth or more, but less than one-third, (2) one-third or more, but less than a majority or (3) a majority or more, of all of the voting power of the corporation in the election of directors. Once an acquirer crosses one of these thresholds, shares that it acquired in the transaction taking it over the threshold and within the 90 days immediately preceding the date when the acquiring person acquired or offered to acquire a controlling interest become "control shares" to which the voting restrictions described above apply. While these statutes permit a corporation to opt out of these protective provisions in its articles of incorporation or bylaws, our articles of incorporation and bylaws do not include any such opt-out provision.

Further, NRS 78.139 also provides that directors may resist a change or potential change in control of the corporation if the board of directors determines that the change or potential change is opposed to or not in the best interest of the corporation upon consideration of any relevant facts, circumstances, contingencies or constituencies pursuant to NRS 78.138(4).

Our net operating loss carryforwards and certain other tax attributes may be subject to limitations. The net operating loss carryforwards and certain other tax attributes of us may also be subject to limitations as a result of certain prior ownership changes.

In general, a corporation that undergoes an "ownership change" as defined in Section 382 of the United States Internal Revenue Code of 1986, as amended, is subject to limitations on its ability to utilize its pre-change net operating loss carryforwards to offset future taxable income. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders, generally stockholders beneficially owning five percent or more of a corporation's common stock, applying certain look-through and aggregation rules, increases by more than 50 percentage points over such stockholders' lowest percentage ownership during the testing period, generally three years. We may have experienced ownership changes in the past and may experience ownership changes in the future. It is possible that our net operating loss carryforwards and certain other tax attributes may also be subject to limitation as a result of ownership changes in the past. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our net operating loss carryforwards and certain other tax attributes, which could have a material adverse effect on cash flow and results of operations.

We are a "smaller reporting company" and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are a smaller reporting company, as defined in Rule 12b-2 under the Exchange Act, and we will remain a smaller reporting company until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are less than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter. Smaller reporting companies are permitted to rely on exemptions from certain disclosure requirements that are applicable to other public companies, including not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting, reduced disclosure obligations regarding executive compensation and not being required to provide disclosures regarding quantitative and qualitative disclosures about market risk in our Annual Reports on Form 10-K.

We have elected to take advantage of certain of these exemptions in the past and may continue to choose to take advantage of some, but not all, of them in the future. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, which may result in additional stock price volatility.

We may never pay dividends on our common stock so any returns would be limited to the appreciation of our stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate we will declare or pay any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

General Risk Factors

An active trading market for our common stock may not be sustained, and you may not be able to resell your common stock at a desired market price.

If no active trading market for our common stock is sustained, you may be unable to sell your shares when you wish to sell them or at a price that you consider attractive or satisfactory. The lack of an active market may also adversely affect our ability to raise capital by selling securities in the future or impair our ability to acquire or in-license other product candidates, businesses or technologies using our shares as consideration.

Our internal control over financial reporting may not meet the standards required by Section 404 of the Sarbanes-Oxley Act, and failure to achieve and 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 share price.

Our management is required to report on the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation.

In connection with the implementation of the necessary procedures and practices related to internal control over financial reporting, we may identify deficiencies or material weaknesses that we may not be able to remediate in time to meet the deadline imposed by the Sarbanes-Oxley Act for compliance with the requirements of Section 404. In addition, we may encounter problems or delays in completing the implementation of any requested improvements and, when required, receiving a favorable attestation in connection with the attestation provided by our independent registered public accounting firm. Failure to achieve and maintain an effective internal control environment could have a material adverse effect on our business, financial condition and results of operations and could limit our ability to report our financial results accurately and in a timely manner.

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

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline.

The impact of the Russian invasion of Ukraine on the global economy, energy supplies and raw materials is uncertain, but may prove to negatively impact our business and operations.

The short and long-term implications of Russia's invasion of Ukraine are difficult to predict at this time. We continue to monitor any adverse impact that the outbreak of war in Ukraine and the subsequent institution of sanctions against Russia by the United States and several European and Asian countries may have on the global economy in general, on our business and operations and on the businesses and operations of our suppliers and other third parties with which we conduct business. For example, a prolonged conflict may result in increased inflation, escalating energy prices and constrained availability, and thus increasing costs, of raw materials. We will continue to monitor this fluid situation and develop contingency plans as necessary to address any disruptions to our business operations as they develop. To the extent the war in Ukraine may adversely affect our business as discussed herein, it may also have the effect of heightening many of the other risks described herein. Such risks include, but are not limited to, adverse effects on macroeconomic conditions, including inflation; disruptions to our technology infrastructure, including through cyberattack, ransom attack, or cyber-intrusion; adverse changes in international trade policies and relations; disruptions in global supply chains; and constraints, volatility, or disruption in the capital markets, any of which could negatively affect our business and financial condition.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We currently lease one corporate office property in New York, New York, as our corporate office space for approximately 300 square feet. We believe that our leased facility is generally well maintained and in good operating condition and that the space is suitable and sufficient for our operational needs.

ITEM 3. LEGAL PROCEEDINGS

We may be a party to certain other litigation that is either judged to be not material or that arises in the ordinary course of business from time to time. We intend to vigorously defend our interests in these matters. We expect that the resolution of these matters will not have a material adverse effect on our business, financial condition or results of operations. However, due to the uncertainties inherent in litigation, no assurance can be given as to the outcome of these proceedings.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II.

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock is traded on the Nasdaq Capital Market under the symbol "SEEL." Before January 24, 2019, our common stock was trading under the ticker symbol "APRI". The daily market activity and closing prices of our common stock can be found at www.nasdaq.com.

On February 24, 2023, the last reported sales price for our common stock on the Nasdaq Capital Market was $0.67 per share, and we had approximately 110 holders of record of our common stock. One of our shareholders is Cede & Co., a nominee for Depository Trust Company ("DTC"). Shares of common stock that are held by financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are considered to be held of record by Cede & Co. as one stockholder.

Dividend Policy

We have never declared or paid cash dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on our capital stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if the common stock price appreciates.

Unregistered Sales of Equity Securities and Use of Proceeds

None.

ITEM 6. [RESERVED]

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

Overview

We are a clinical-stage biopharmaceutical company focused on achieving efficient development of products that address significant unmet needs in Central Nervous System ("CNS") disorders and other rare disorders.

Impact of COVID-19

Beginning in the fourth quarter of 2021 and through the fourth quarter of 2022, we experienced a slowdown in patient enrollment primarily due to staffing issues at our study sites related to the spike in COVID-19 cases due to the Omicron variant and its sub-variants. Recently, we have seen staffing issues improving, but we cannot be certain that this trend will continue as additional variants emerge and COVID-19 continues to circulate and spread. However, the pandemic has not materially affected our liquidity as we maintain our resources in the form of cash.

In addition, although preventative measures taken to date did not have a material adverse impact on our business during 2022, the continued impact of the COVID-19 pandemic on our business, financial condition and results of operations is unknown and will depend on future developments and risks, which are highly uncertain and cannot be predicted. These developments and risks include, among others, the duration and severity of the COVID-19 pandemic, the emergence or spread of new COVID-19 variants, the impact on the capital markets, the impact on our partners and the regulatory agencies that oversee our sector and any additional preventative and protective actions that governmental authorities, or we, may implement, any of which may result in an extended period of business disruption, including potential delays in commencing future clinical trials, or in completing enrollment for any clinical trials we may commence or in the U.S. Food and Drug Administration ("FDA") or other regulatory agencies conducting in-person inspections or accommodations for alternatives to in-person inspections. Any resulting financial impact cannot be reasonably estimated at this time, but the COVID-19 pandemic may force us to make adjustments to our business, our plans and our timeline for developing assets, including our programs. In addition, the pandemic is currently not anticipated to have a material adverse impact on our business, financial condition and results of operations, including our ability to raise additional capital. See Part I, Item 1A, Risk Factors, for an additional discussion of risks related to COVID-19.

Our business model is to advance multiple late-stage therapeutic candidates with proven mechanisms of action that address large markets with unmet medical needs and for which there is a strong economic and scientific rationale for development.

Our product development pipeline is as follows:

Product	Indication	Development Phase	Development Status
SLS-002 Intranasal Racemic Ketamine	Acute Suicidal Ideation and Behavior (ASIB) in Major Depressive Disorder (MDD)	Phase II	Completed open-label patient enrollment and announced the initial topline data from Part 1 of the proof-of-concept study on May 17, 2021; enrollment of Part 2 of a registration directed study ongoing; data readout for Part 2 expected in the third quarter of 2023
SLS-005 IV Trehalose	Amyotrophic Lateral Sclerosis (ALS)	Phase II/III	Completed enrollment of final participants in February 2023 in the registrational study; data readout expected in late 2023
	Spinocerebellar Ataxia (SCA)	Phase IIb/III	In October 2022, we announced dosing of the first participant in the registrational study; enrollment ongoing
	Huntington's Disease (HD) and Alzheimer's Disease (AD)	Phase II	Obtaining biomarker activity
SLS-004 Gene Therapy	Parkinson's Disease (PD)	Pre-IND	Preclinical *in vivo* studies ongoing; in December 2022, we announced partial results from a study demonstrating downregulation of α-synuclein
SLS-007 Peptide Inhibitor	Parkinson's Disease (PD)	Pre-IND	Preclinical study completed and analysis of the results ongoing; next steps for development of this program will be decided in concert with SLS-004 results and readouts, as both target the same pathway upstream

Lead Programs

Our lead programs are currently SLS-002 for the potential treatment of Acute Suicidal Ideation and Behavior ("ASIB") in patients with Major Depressive Disorder ("MDD") and SLS-005 for the potential treatment of Amyotrophic Lateral Sclerosis ("ALS") and Spinocerebellar Ataxia ("SCA"). SLS-005 for the potential treatment of Sanfilippo Syndrome currently requires additional natural history data, which is being considered.

SLS-002 is intranasal racemic ketamine with two investigational new drug applications ("INDs"). The lead program is focused on the treatment of ASIB in MDD. SLS-002 was originally derived from a Javelin Pharmaceuticals, Inc./Hospira, Inc. program with 16 clinical studies involving approximately 500 subjects. SLS-002 is being developed to address an unmet need for an efficacious drug to treat suicidality in the United States. Traditionally, anti-depressants have been used in this setting but many of the existing treatments are known to contribute to an increased risk of suicidal thoughts in some circumstances, and if and when they are effective, it often takes weeks for the full therapeutic effect to be manifested. We believe there is a large opportunity in the United States and European markets for products in this space. Based on information gathered from the databases of the Agency for Healthcare Research and Quality, there were approximately 1.48 million visits to emergency rooms for suicidal ideation or suicide attempts in 2017 in the United States alone. Experimental studies suggest ketamine has the potential to be a rapid, effective treatment for depression and suicidality.

The clinical development program for SLS-002 includes two parallel healthy volunteer studies (Phase I). We announced interim data from our Phase I study of SLS-002 during the quarterly period ended March 31, 2020. As a result, in March 2020, we completed a Type C meeting with the U.S. Food and Drug Administration ("FDA") and received guidance to conduct a Phase II proof of concept ("PoC") study of SLS-002 for ASIB in patients with MDD, to support the further clinical development of this product candidate, together with nonclinical data under development.

As a result of the Type C meeting and the Fast Track designation for SLS-002 for the treatment of ASIB in patients with MDD, we believe we are well positioned to pursue the FDA's expedited programs for drug development and review.

On June 23, 2020, we announced the final safety data from our Phase I pharmacokinetics/pharmacodynamics study of intranasal racemic ketamine (SLS-002) as well as the planned design of a Phase II double blind, placebo-controlled PoC study for ASIB in subjects with MDD. We initiated this PoC study in two parts: Part 1 was an open-label study of 17 subjects, and is being followed by Part 2, which is a double blind, placebo-controlled study of approximately 175 subjects. On January 15, 2021, we announced dosing of the first subjects in Part 1 of the PoC study. On March 5, 2021, we announced the completion of open-label enrollment of subjects in Part 1 of the PoC study. On May 17, 2021, we announced positive topline data from Part 1 of the POC study, the open-label cohort, of our study of SLS-002 (intranasal racemic ketamine), demonstrating a significant treatment effect and a well-tolerated safety profile for ASIB in patients with MDD. This study enrolled 17 subjects diagnosed with MDD requiring psychiatric hospitalization due to significant risk of suicide with a baseline score of ≥ 28 points on the Montgomery-Åsberg Depression Rating Scale ("MADRS"), a score of 5 or 6 on MADRS Item-10, a score of ≥ 15 points on the Sheehan-Suicidality Tracking Scale (S-STS) total score and a history of previous suicide attempt(s), as confirmed on the Columbia Suicide Severity Rating Scale (C-SSRS) with a history of at least one actual attempt, or if the attempt was interrupted or aborted, is judged to have been serious in intent. SLS-002 demonstrated a 76.5% response rate (response meaning 50% reduction from baseline) in the primary endpoint on MADRS twenty-four hours after first dose, with a mean reduction in total score from 39.4 to 14.5 points.

On July 6, 2021, we announced dosing of the first subject in Part 2 of the planned registration directed study. Based on feedback from a Type C meeting with the FDA in June 2021, we increased the subjects in Part 2 to increase the sample size and power to support a potential marketing application.

SLS-005 is IV trehalose, a protein stabilizer that crosses the blood-brain-barrier and activates autophagy and the lysosomal pathway. Based on preclinical and *in vitro* studies, there is a sound scientific rationale for developing trehalose for the treatment of ALS, SCA and other indications such as Sanfilippo Syndrome. Trehalose is a low molecular weight disaccharide (0.342 kDa) that protects against pathological processes in cells. It has been shown to penetrate muscle and cross the blood-brain-barrier. In animal models of several diseases associated with abnormal cellular protein aggregation, it has been shown to reduce pathological aggregation of misfolded proteins as well as to activate autophagy pathways through the activation of Transcription Factor EB ("TFEB"), a key factor in lysosomal and autophagy gene expression. Activation of TFEB is an emerging therapeutic target for a number of diseases with pathologic accumulation of storage material.

Trehalose 90.5 mg/mL IV solution has demonstrated promising clinical potential in prior Phase II clinical development for oculopharyngeal muscular dystrophy ("OPMD") and spinocerebellar ataxia type 3 ("SCA3"), also known as Machado Joseph disease, with no significant safety signals to date and encouraging efficacy results. Pathological accumulation of protein aggregates within cells, whether in the CNS or in muscle, eventually leads to loss of function and ultimately cell death. Prior preclinical studies indicate that this platform has the potential to prevent mutant protein aggregation in other devastating PolyA/PolyQ diseases.

We own three United States patents for parenteral administration of trehalose for patients with OPMD and SCA3, all of which are expected to expire in 2034. In addition, Orphan Drug Designation ("ODD") for OPMD and SCA3 has been secured in the United States and in the European Union ("EU"). In February 2019, we assumed a collaborative agreement, turned subsequently into a research grant, with Team Sanfilippo Foundation ("TSF"), a nonprofit medical research foundation founded by parents of children with Sanfilippo Syndrome. On April 30, 2020, we were granted ODD for SLS-005 in Sanfilippo Syndrome from the FDA. SLS-005 was previously granted ODD from the FDA and European Medicines Agency for SCA3 and OPMD as well as Fast Track designation for OPMD. On August 25, 2020, we were issued U.S. patent number 10,751,353 titled "COMPOSITIONS AND METHODS FOR TREATING AN AGGREGATION DISEASE OR DISORDER" which relates to trehalose (SLS-005). The issued patent covers the method of use for trehalose (SLS-005) formulation for treating a disease or disorder selected from any one of the following: spinal and bulbar muscular atrophy, dentatombral-pallidoluysian atrophy, Pick's disease, corticobasal degeneration, progressive supranuclear palsy, frontotemporal dementia or parkinsonism linked to chromosome 17. On May 15, 2020, we were granted Rare Pediatric Disease Designation ("RPDD") for SLS-005 in Sanfilippo Syndrome from the FDA. RPDD is an incentive program created under the Federal Food, Drug, and Cosmetic Act to encourage the development of new therapies for the prevention and treatment of certain rare pediatric diseases. On May 27, 2021, we announced that we were granted ODD for SLS-005 in ALS from the European Medicines Agency. In December 2020, we announced the selection of SLS-005 for the Healey ALS platform trial led by Harvard Medical School, Massachusetts. The Healey ALS platform trial is designed to study multiple potential treatments for ALS simultaneously. The platform trial model aims to greatly accelerate the study access, reduce costs and shorten development timelines. On February 28, 2022, we announced the dosing of the first participants in the Healey ALS platform trial. In November 2021, we announced the FDA acceptance of an IND and grant of Fast Track designation for SLS-005 for the treatment of SCA. In July 2022, we announced dosing of the first patient in an open-label basket study in Australia for the treatment of patients with ALS, SCA, and Huntington's disease ("HD"). In October 2022, we also announced the dosing of the first participant in the registrational phase II/III study for the treatment of SCA.

Additionally, we are developing several preclinical programs, most of which have well-defined mechanisms of action, including SLS-004, licensed from Duke University, and SLS-007, licensed from The Regents of the University of California, for the potential treatment of Parkinson's Disease ("PD").

Strategy and Ongoing Programs

SLS-002: The clinical development program for SLS-002 includes two parallel healthy volunteer studies (Phase I). Following these Phase I studies, we completed a Type C meeting with the FDA in March 2020 and received guidance to conduct a Phase II PoC study of SLS-002 for ASIB in subjects with MDD. We released topline data for Part 1 of our open-label study on May 17, 2021. We initiated enrollment in Part 2 of the registration directed study on July 6, 2021, and we anticipate enrollment completing in mid-2023, with a data readout for Part 2 expected in the third quarter of 2023.

SLS-005: We completed enrollment in February 2023 for a clinical study in ALS and began enrollment for a clinical study in SCA in October 2020. In December 2020, we announced the selection of SLS-005 for the Healey ALS platform trial led by Harvard Medical School, Massachusetts. The Healey ALS platform trial is designed to study multiple potential treatments for ALS simultaneously. The platform trial model aims to greatly accelerate the study access, reduce costs, and shorten development timelines. On February 28, 2022, we announced dosing of the first participants in the Healey ALS platform trial. In November 2021, we announced the FDA acceptance of an IND and grant of Fast Track designation for SLS-005 for the treatment of SCA. In July 2022, we announced dosing of the first patient in an open-label basket study in Australia for the treatment of patients with ALS, SCA, and HD. In October 2022, we also announced the dosing of the first participant in the registrational phase II/III study for the treatment of SCA. During 2022, we received regulatory approval in Australia to commence a study pursuing collection of certain biomarker data in Alzheimer's Disease. We are continuing to consider trials in Sanfilippo Syndrome and are seeking more natural history data based on the guidance from regulatory agencies. In February 2023, we announced the completion of enrollment of the study and data readout is expected in late 2023.

SLS-004 is an all-in-one lentiviral vector, targeted for gene editing through DNA methylation within intron 1 of the synuclein alpha ("SNCA") gene that expresses alpha-synuclein protein. SLS-004, when delivered to dopaminergic neurons derived from human induced pluripotent stem cells of a PD patient, modified the expression on alpha-synuclein ("α-synuclein") and exhibited reversal of the disease-related cellular-phenotype characteristics of the neurons. The role of mutated SNCA in PD pathogenesis and the need to maintain the normal physiological levels of α-synuclein protein emphasize the yet unmet need to develop new therapeutic strategies, such as SLS-004, targeting the regulatory mechanism of α-synuclein expression. On May 28, 2020, we announced the initiation of a preclinical study of SLS-004 in PD through an all-in-one lentiviral vector targeting the SNCA gene. We are constructing a bimodular viral system harboring an endogenous α-synuclein transgene and inducible regulated repressive CRISPR/dCas9-unit to achieve suppression of PD-related pathologies. On July 7, 2021, we announced positive *in vivo* data demonstrating down-regulation of SNCA mRNA and protein expression under this study. In December 2022, we announced *in vivo* data demonstrating that a single dose of SLS-004 was successful in reversing some of the key hallmarks of PD in a humanized mouse model. These findings observed in an *in vivo* humanized PD model validate and extend prior findings from *in vitro* data using SLS-004. SLS-004 demonstrated therapeutically desirable change in SNCA expression that led to reversing the key hallmarks of PD in the model towards normal physiological levels, indicating disease modifying effect of single dose administration of SLS-004, a CRISPR/dCas-9 based gene therapy for PD.

SLS-007 is a rationally designed peptide-based approach, targeting the nonamyloid component core ("NACore") of α-synuclein to inhibit the protein from aggregation. Recent *in vitro* and cell culture research has shown that SLS-007 has the ability to stop the propagation and seeding of α- synuclein aggregates. We will evaluate the potential for *in vivo* delivery of SLS-007 in a PD transgenic mice model. The goal will be to establish *in vivo* pharmacokinetics/pharmacodynamics and target engagement parameters of SLS-007, a family of anti- α -synuclein peptidic inhibitors. On June 25, 2020, we announced the initiation of a preclinical study of SLS-007 in PD delivered through an adeno associated viral ("AAV") vector targeting the non-amyloid component core of α-synuclein. We have initiated an *in vivo* preclinical study of SLS-007 in rodents to assess the ability of two specific novel peptides, S62 and S71, delivered via AAV1/2 viral vector, to protect dopaminergic function in the AAV A53T overexpression mice model of PD. Production of AAV1/2 vectors encoding each of the two novel peptides incorporating hemagglutinin tags has already been completed. The results are currently being analyzed and the next steps for development of this program will be decided in concert with SLS-004 results and readouts, as both target the same pathway upstream.

We intend to become a leading biopharmaceutical company focused on neurological and psychiatric disorders, including orphan indications. Our business strategy includes:

- advancing SLS-002 in ASIB in MDD and post-traumatic stress disorder;
- advancing SLS-004 in PD;
- advancing SLS-005 in ALS, SCA, HD and Sanfilippo Syndrome;
- advancing new formulations of SLS-005 in neurological diseases; and
- acquiring synergistic assets in the CNS therapy space through licensing and partnerships.

We also have two legacy product candidates: a product candidate in the United States for the treatment of erectile dysfunction, which we in-licensed from Warner Chilcott Company, Inc., now a subsidiary of Allergan plc; and a product candidate which has completed a Phase IIa clinical trial for the treatment of Raynaud's Phenomenon, secondary to scleroderma, for which we own worldwide rights.

Results of Operations

Operating Expense

Operating expense for the years ended December 31, 2022 and 2021 was as follows (in thousands, except percentages):

	Year Ended December 31,		Year Ended December 31, 2022 vs 2021	
	2022	2021	$ Change	% Change
Operating expense				
Research and development	$ 58,620	$ 46,649	$ 11,971	26 %
General and administrative	12,296	15,020	(2,724)	(18)%
Total operating expense	$ 70,916	$ 61,669	$ 9,247	15 %

Research and Development Expenses

Research and development ("R&D") costs are expensed as they are incurred and include the cost of compensation and related expenses, as well as expenses for third parties who conduct R&D on our behalf. The $12.0 million increase in R&D expense during the year ended December 31, 2022, as compared to the same period in 2021, is detailed as follows (in thousands, except percentages):

	Year Ended December 31,		Year Ended December 31, 2022 vs 2021	
	2022	2021	$ Change	% Change
Research and development expenses				
License payments	$ 6,295	$ 18,140	$ (11,845)	(65)%
Clinical trial expenses	38,426	17,382	21,044	121 %
Manufacturing expenses	6,948	5,592	1,356	24 %
Employee compensation	3,821	3,370	451	13 %
Contract consulting expenses	2,219	1,454	765	53 %
Other research and development expenses	911	711	200	28 %
Total research and development expenses	$ 58,620	$ 46,649	$ 11,971	26 %

The $12.0 million increase in R&D expense during the year ended December 31, 2022, as compared to the same period in 2021, resulted primarily from an increase in (i) clinical trial costs of approximately $21.0 million, mainly due to our ongoing clinical trials of SLS-002 and SLS-005, and (ii) manufacturing costs to support increased clinical activity of $1.4 million. These increases were partially offset by a decrease in license fee expenses of approximately $11.9 million, mainly related to the license agreement with iX Biopharma Europe Ltd. in 2021.

General and Administrative Expenses

General and administrative ("G&A") costs include expenses for personnel, finance, legal, business development and investor relations. G&A expenses decreased by $2.7 million during the year ended December 31, 2022, as compared to the same period in 2021. This decrease was primarily due to (i) a decrease in non-cash stock-based compensation of approximately $3.5 million, primarily related to $4.9 million in expense due to vesting of a performance stock unit award in the fourth quarter of 2021 that was subsequently cancelled in the first quarter of 2022, and (ii) a decrease in costs including, but not limited to, legal fees of approximately $0.5 million during the year ended December 31, 2022. This decrease was partially offset by increases in employee costs of $0.6 million and investor relations costs of $0.4 million during the year ended December 31, 2022.

Other Income and Expense

Other income and expense for the years ended December 31, 2022 and 2021 was as follows (in thousands):

	Year Ended December 31,		
	2022	2021	$ Change
Other income (expense)			
Interest income	$ 121	$ 113	$ 8
Interest expense	(14)	(1,598)	1,584
Change in fair value of derivative liability	—	(369)	369
Change in fair value of convertible notes	(3,017)	230	(3,247)
Net loss on extinguishment of debt	—	(2,387)	2,387
Gain on forgiveness of debt	—	149	(149)
Change in fair value of warrant liabilities	292	(517)	809
Total other income (expense)	$ (2,618)	$ (4,379)	$ 1,761

Interest Income

Interest income was $121,000 and $113,000 for the years ended December 31, 2022 and 2021, respectively. The increase in interest income was primarily related to higher interest rates during the year ended December 31, 2022 compared to the year ended December 31, 2021.

Interest Expense

Interest expense was $14,000 and $1.6 million for the years ended December 31, 2022 and 2021, respectively. The decrease was due to our repayment of the December 2020 convertible notes during 2021.

Change in Fair Value of Derivative Liability

Change in fair value of derivative liability was $0 and $0.4 million for the years ended December 31, 2022 and 2021. This change is due to the revaluation of the embedded derivative resulting from our license agreement with iX Biopharma Europe Ltd., which was revalued at December 31, 2021, with changes in fair value reflected in earnings. The derivative liability was settled in January 2022.

Change in Fair Value of Convertible Notes

Change in fair value of convertible notes was $3.0 million and $0.2 million for the years ended December 31, 2022 and 2021, respectively. This change is due to our 2021 convertible notes issued in November 2021 and December 2021, which have been accounted for under the fair value option and are revalued at each reporting period, with changes in fair value reflected in earnings.

Net Loss on Extinguishment of Debt

Net loss on extinguishment of debt was $0 and $2.4 million for the years ended December 31, 2022 and 2021, respectively. This loss was primarily due to the termination agreement with Lind Global Asset Management II, LLC ("Lind") during the year ended December 31, 2021, whereby we issued Lind 406,250 shares with a fair value of $1.4 million, as well as losses on extinguishments recognized on other principal payments during 2021 on our 2020 convertible notes.

Gain on Forgiveness of Debt

Gain on forgiveness of debt was $0 and $149,000 for the years ended December 31, 2022 and 2021, respectively. This gain was due to the forgiveness of our outstanding PPP loan, which we received in June 2021.

Change in Fair Value of Warrant Liability

The fair value of warrant liability was $0.1 million and $0.4 million at December 31, 2022 and 2021, respectively. The change in fair value of warrant liabilities of $0.3 million during the year ended December 31, 2022 is due to revaluation of the Series A warrants during such period. The change in fair value of warrant liabilities of $0.5 million during the year ended December 31, 2021 was due to revaluation of the Series A warrants during such period.

Liquidity, Capital Resources and Financial Condition

We have generated limited revenues, incurred operating losses since inception, and we expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of December 31, 2022, we had $15.5 million in cash and an accumulated deficit of $214.7 million. We have historically funded our operations through the issuance of convertible notes (the "Notes") (see Note 9 to our consolidated financial statements), the sale of common stock (see Note 6 to our consolidated financial statements) and the exercise of warrants (see Note 10 to our consolidated financial statements).

On May 12, 2022, we entered into an Open Market Sale Agreement℠ (the "Sale Agreement") with Jefferies LLC, as sales agent (the "Agent"), pursuant to which we may offer and sell shares of our common stock from time to time through the Agent (the "Offering"). We also filed a prospectus supplement, dated May 12, 2022, with the SEC in connection with the Offering (the "Prospectus Supplement") under our existing shelf Registration Statement on Form S-3, as amended (File No. 333-251356), which became effective on December 23, 2020 (the "Registration Statement"). Pursuant to the Prospectus Supplement, we may offer and sell shares having an aggregate offering price of up to $50.0 million. Under the terms of the Sale Agreement, the Agent is entitled to a commission at a fixed rate of 3.0% of the gross proceeds from each sale of shares under the Sale Agreement. We also reimburse the Agent for certain expenses incurred in connection with the Sale Agreement, and agreed to provide indemnification and contribution to the Agent with respect to certain liabilities, including liabilities under the Securities Act of 1933, as amended (the "Securities Act"), and the Exchange Act. During the year ended December 31, 2022, we sold an aggregate of 350,000 shares under the Sale Agreement, receiving net proceeds of $0.5 million. We currently intend to use any net proceeds from the Offering for general corporate purposes and to advance the development of our product candidates.

As of December 31, 2022, we had approximately $94.6 million available under the Registration Statement (inclusive of the $49.5 million that remained allocated to sales of shares of our common stock pursuant to the Sale Agreement as of such date).

On November 23, 2021, we entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with Lind Global Asset Management V, LLC ("Lind V") pursuant to which, among other things, on November 23, 2021, we issued and sold to Lind V, in a private placement transaction, in exchange for the payment by Lind V of $20.0 million, (1) a convertible promissory note (the "2021 Note") in an aggregate principal amount of $22.0 million, which will bear no interest until the first anniversary of the issuance of the First Note and will thereafter bear interest at a rate of 5% per annum, and mature on November 23, 2024, and (2) 534,759 shares (the "2021 Closing Shares") of our common stock.

See Note 9 to our consolidated financial statements for further discussion.

On December 2, 2021, we entered into two separate securities purchase agreements with certain accredited investors on substantially the same terms as the Securities Purchase Agreement, pursuant to which we sold, in private placement transactions, in exchange for the payment by the accredited investors of an aggregate of $201,534, (i) convertible promissory notes (the "December 2021 Notes") in an aggregate principal amount of $221,688, which will bear no interest and mature on December 2, 2024, and (ii) an aggregate of 5,388 shares of our common stock. The December 2021 Notes have substantially the same terms as the 2021 Note. On February 22, 2023, the December 2021 Notes were repaid in full.

On May 24, 2021, we completed an underwritten public offering pursuant to which we sold 22,258,066 shares of our common stock at a price to the public of $3.10 per share, which included the exercise in full by the underwriter of its option to purchase up to 2,903,226 additional shares of common stock. The net proceeds to us from the offering were $64.5 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us (see Note 6 to our consolidated financial statements).

On January 28, 2021, we completed an underwritten public offering pursuant to which we sold 17,530,488 shares of our common stock at a price to the public of $2.05 per share, which included the exercise in full by the underwriter of its option to purchase up to 2,286,585 additional shares of common stock. The net proceeds to us from the offering were $33.5 million, after deducting underwriting discounts and commissions and other offering expenses payable by us (see Note 6 to our consolidated financial statements).

We expect to use the net proceeds from the above transactions primarily for general corporate purposes, which may include financing our normal business operations, developing new or existing product candidates, and funding capital expenditures, acquisitions and investments.

We evaluated whether there are any conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year beyond the filing of this Annual Report on Form 10-K. Based on such evaluation and our current plans (including the ongoing clinical programs for SLS-002, SLS-005, and other product candidates), which are subject to change, management believes that our existing cash and cash equivalents as of December 31, 2022 are not sufficient to satisfy our operating cash needs for the year after the filing of this Annual Report on Form 10-K, and there is substantial doubt of our ability to continue as a going concern within one year beyond the date of filing of this Annual Report on Form 10-K.

We currently have an effective shelf registration statement on Form S-3 filed with the SEC. We may use the shelf registration statement on Form S-3 to offer from time to time any combination of debt securities, common and preferred stock and warrants, and, as of the date hereof, a total of $94.6 million of securities remains available for issuance pursuant to the shelf registration statement.

The accompanying audited consolidated financial statements have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to our ability to continue as a going concern.

Our future liquidity and capital funding requirements will depend on numerous factors, including:

- our ability to raise additional funds to finance our operations;
- our ability to maintain compliance with the listing requirements of The Nasdaq Capital Market;
- the outcome, costs and timing of any clinical trial results for our current or future product candidates;
- potential litigation expenses;
- the emergence and effect of competing or complementary products or product candidates;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our ability to retain our current employees and the need and ability to hire additional management and scientific and medical personnel;
- the terms and timing of any collaborative, licensing or other arrangements that we have or may establish;
- the trading price of our common stock; and
- our ability to increase the number of authorized shares outstanding to facilitate future financing events.

We may need to raise substantial additional funds, and if we do so, we may do so through one or more of the following: issuance of additional debt, equity, or both and/or the completion of a licensing or other commercial transaction for one or more of our product candidates. If we are unable to maintain sufficient financial resources, our business, financial condition and results of operations will be materially and adversely affected. This could adversely affect future development and business activities, operations and business plans, such as future clinical studies and/or other future ventures. There can be no assurance that we will be able to obtain the needed financing on acceptable terms or at all. Additionally, equity or convertible debt financings may have a dilutive effect on the holdings of our existing stockholders. No assurances can be given that we will be able to obtain additional financing.

Cash Flow Summary

The following table summarizes selected items in our consolidated statements of cash flows (in thousands):

	Year ended December 31,	
	2022	2021
Net cash (used in) provided by operations		
Net cash used in operating activities	$ (61,604)	$ (48,995)
Net cash (used in) provided by financing activities	(1,597)	112,067
Net (decrease) increase in cash	$ (63,201)	$ 63,072

Operating Activities

Cash used in operating activities of $61.6 million in the year ended December 31, 2022 was primarily due to the net loss of $73.5 million, which was partially offset by changes in operating assets and liabilities of $2.8 million and stock compensation expense of $5.1 million.

Cash used in operating activities of $49.0 million in the year ended December 31, 2021 was primarily due to the net loss of $66.0 million and changes in operating assets and liabilities of $1.4 million, which was partially offset by $8.3 million in stock compensation expense and $5.6 million in non-cash research and development expense of licenses acquired.

Investing Activities

No cash was used in investing activities during the years ended December 31, 2022 or 2021.

Financing Activities

Cash used in financing activities of $1.6 million in the year ended December 31, 2022 was primarily due to the principal payments for our convertible notes, which were partially offset by the sale of shares of our common stock pursuant to the Sale Agreement of approximately $0.5 million.

Cash provided by financing activities of $112.1 million in the year ended December 31, 2021 was primarily due to the proceeds from our May 2021 and January 2021 public offerings, as well as proceeds from the issuance and sale of the 2021 Note and the 2021 Closing Shares.

Contractual Obligations

We have entered into long-term agreements with certain manufacturers and suppliers that require us to make contractual payment to these organizations. Further, we have entered into certain material contracts with contract research organizations for our SLS-002, SLS-005, and other clinical programs, which include varying cancellation fees in the event we delay or cancel our studies with them. We expect to enter into additional collaborative research, contract research, manufacturing, and supplier agreements in the future, which may require up-front payments and long-term commitments of cash.

Recent Accounting Pronouncements

See Note 1 to our consolidated financial statements for a discussion of recent accounting pronouncements and their effect, if any, on us.

Critical Accounting Estimates and Policies

The preparation of financial statements in accordance with United States generally accepted accounting principles ("GAAP") requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. Management bases its estimates on historical experience, market and other conditions, and various other assumptions it believes to be reasonable. Although these estimates are based on management's best knowledge of current events and actions that may impact us in the future, the estimation process is, by its nature, uncertain given that estimates depend on events over which we may not have control. If market and other conditions change from those that we anticipate, our consolidated financial statements may be materially affected. In addition, if our assumptions change, we may need to revise our estimates, or take other corrective actions, either of which may also have a material effect in our consolidated financial statements. We review our estimates, judgments, and assumptions used in our accounting practices periodically and reflect the effects of revisions in the period in which they are deemed to be necessary. We believe that these estimates are reasonable; however, our actual results may differ from these estimates.

We believe that the following critical accounting policies and estimates have a higher degree of inherent uncertainty and require our most significant judgments:

Accrual of Research and Development Expenses

Research and development costs are expensed as incurred and include salaries and benefits; costs paid to third-party contractors to perform research, conduct clinical trials, develop and manufacture pre-approval drug materials and delivery devices. Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. Invoicing from third-party contractors for services performed can lag several months. We accrue the costs of services rendered in connection with third-party contractor activities based on our estimate of management fees, site management and monitoring costs and data management costs. Differences between actual clinical trial costs from estimated clinical trial costs have not been material and are adjusted for in the period in which they become known.

Stock Based Compensation

Stock based compensation expense includes charges related to options awards to employees and directors. The estimated grant date fair value of stock options granted to employees and directors is calculated based upon the closing stock price of our common stock on the date of the grant and recognized as stock-based compensation expense over the expected service period, which is typically approximated by the vesting period.

We estimate the fair value of each option award on the date of grant using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires us to estimate our dividend yield rate, expected volatility and risk-free interest rate over the life of the option. The use of estimates on these factors may cause the fair value of the option to be under or overestimated (see Note 11 to our consolidated financial statements for the current estimates used in the Black-Scholes option pricing model).

Valuation of Warrant Liability

Our outstanding Series A Warrants are classified as liabilities in the accompanying consolidated balance sheets as they contain provisions that are considered outside of our control, such as requiring us to maintain active registration of the shares underlying such warrants. The warrants were recorded at fair value using the Black-Scholes option pricing model. The fair value of these warrants is re-measured at each financial reporting period with any changes in fair value being recognized as a component of other income (expense) in the accompanying consolidated statements of operations.

Valuation of Convertible Notes

Our outstanding 2021 Note and the December 2021 Notes are accounted for under the fair value option in the accompanying consolidated balance sheets, as permitted under Accounting Standards Codification Topic 825, Financial Instruments. The convertible notes were recorded at fair value using a Monte-Carlo simulation model. The convertible notes are re-measured at each financial reporting period with any changes in fair value being recognized as a component of other income (expense) in the accompanying consolidated statements of operations.

The fair value of our 2021 Note and the December 2021 notes are based on significant inputs including volatility and discount rate, which are not observable in the market and which causes them to be classified as a Level 3 measurement within the fair value hierarchy. These valuations use assumptions and estimates we believe would be made by a market participant in making the same valuation. We assess these assumptions and estimates on an on-going basis as additional data impacting the assumptions and estimates are obtained.

The fair value of the 2021 Note and the December 2021 notes may change significantly as additional data is obtained, impacting our assumptions used to estimate the fair value. In evaluating this information, considerable judgment is required to interpret the data used to develop the assumptions and estimates. The estimates of fair value may not be indicative of the amounts that could be realized in a current market exchange. Accordingly, the use of different market assumptions and/or different valuation techniques may have a material effect on the estimated fair value amounts, and such changes could materially impact our results of operations in future periods.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Seelos Therapeutics, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Seelos Therapeutics, Inc. and subsidiaries (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2022, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit. 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 audit 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 consolidated 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 audit, 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 audit included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matter

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

Assessment of the measurement of fair value of the convertible note with Lind V

As discussed in Notes 4 and 9 to the consolidated financial statements, the Company completed several convertible note offerings during the year ended December 31, 2021, including an offering with Lind Global Asset Management V, LLC (Lind V). The Company received aggregate gross proceeds of $20.2 million from the convertible note offerings, and elected to account for these convertible notes at fair value. The estimated fair value of the convertible notes as of December 31, 2022 was $20.0 million, which included the convertible note with Lind V. The Company used a Monte Carlo simulation model to estimate the fair value of the convertible notes.

We identified the assessment of the measurement of fair value of the convertible note with Lind V as of December 31, 2022 as a critical audit matter. This matter required the involvement of valuation professionals with specialized skills and knowledge to assess the Company's model used to value the convertible note.

The following is the primary procedure we performed to address this critical audit matter. We assessed the valuation model by involving valuation professionals with specialized skills and knowledge who assisted by independently developing a range of fair values of the convertible note with Lind V and comparing it to the amount recorded by the Company.

/s/ KPMG LLP

We have served as the Company's auditor since 2017.

Short Hills, New Jersey
March 9, 2023

Seelos Therapeutics, Inc. and Subsidiaries
Consolidated Balance Sheets
(In thousands, except share and per share data)

	December 31, 2022	December 31, 2021
Assets		
Current assets		
Cash	$ 15,533	$ 78,734
Prepaid expenses and other current assets	7,141	4,727
Total current assets	22,674	83,461
Operating lease right-of-use asset	72	39
Total assets	$ 22,746	$ 83,500
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 3,626	$ 1,693
Accrued expenses	7,282	3,728
Licenses payable	2,195	200
Short-term portion of convertible notes payable, at fair value	11,865	1,030
Derivative liability	—	1,174
Warrant liabilities, at fair value	132	424
Operating lease liability	58	38
Total current liabilities	25,158	8,287
Convertible notes payable, at fair value	8,184	17,890
Operating lease liability, long-term	15	—
Total liabilities	33,357	26,177
Commitments and contingencies (note 12)		
Stockholders' equity (deficit)		
Preferred stock, $0.001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of December 31, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value, 240,000,000 shares authorized, 107,168,256 and 105,500,445 issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	107	105
Additional paid-in-capital	204,026	198,428
Accumulated deficit	(214,744)	(141,210)
Total stockholders' equity (deficit)	(10,611)	57,323
Total liabilities and stockholders' equity (deficit)	$ 22,746	$ 83,500

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

Seelos Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)

	Year Ended December 31,	
	2022	2021
Operating expense		
Research and development	$ 58,620	$ 46,649
General and administrative	12,296	15,020
Total operating expense	70,916	61,669
Loss from operations	(70,916)	(61,669)
Other income (expense)		
Interest income	121	113
Interest expense	(14)	(1,598)
Change in fair value of derivative liability	—	(369)
Change in fair value of convertible notes	(3,017)	230
Net loss on extinguishment of debt	—	(2,387)
Gain on forgiveness of debt	—	149
Change in fair value of warrant liabilities	292	(517)
Total other expense	(2,618)	(4,379)
Net loss and comprehensive loss	$ (73,534)	$ (66,048)
Net loss per share basic and diluted	$ (0.69)	$ (0.73)
Weighted-average common shares outstanding basic and diluted	106,342,171	90,890,061

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

Seelos Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Changes in Stockholders' Equity (Deficit)
(In thousands, except share data)

	Common Stock (Shares)	Common Stock (Amount)	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance as of December 31, 2020	54,535,891	$ 54	$ 77,680	$ (75,162)	$ 2,572
Stock-based compensation expense	—	—	8,347	—	8,347
Issuance of common stock, options exercised	79,138	—	102	—	102
Extinguishment of beneficial conversion feature	—	—	(1,519)	—	(1,519)
Issuance of common stock for license acquired	2,570,266	3	4,830	—	4,833
Issuance of common stock for settlement of debt	406,250	—	1,377	—	1,377
Issuance of common stock for conversion of debt	69,065	—	138	—	138
Issuance of common stock, ESPP	80,009	—	104	—	104
Issuance of common stock, pursuant to 2021 Securities Purchase Agreements	540,147	1	1,051	—	1,052
Warrants exercised for cash	7,431,125	7	8,401	—	8,408
Issuance of common stock, net of issuance costs	39,788,554	40	97,917	—	97,957
Net loss	—	—	—	(66,048)	(66,048)
Balance as of December 31, 2021	105,500,445	$ 105	$ 198,428	$ (141,210)	$ 57,323
Stock-based compensation expense	—	—	5,073	—	5,073
Issuance of common stock, options exercised	6,250	—	8	—	8
Agreement to repurchase common stock	—	—	(740)	—	(740)
Issuance of common stock for prepaid services	200,000	—	167	—	167
Issuance of common stock for license acquired	1,000,000	1	840	—	841
Issuance of common stock in at-the-market offering, net of issuance costs	350,000	1	151	—	152
Issuance of common stock, ESPP	111,561	—	99	—	99
Net loss	—	—	—	(73,534)	(73,534)
Balance as of December 31, 2022	107,168,256	$ 107	$ 204,026	$ (214,744)	$ (10,611)

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

Seelos Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2022	**2021**
Cash flows from operating activities		
Net loss	$ (73,534)	$ (66,048)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	5,073	8,347
Research and development expense - license amendment	841	5,637
Research and development expense - Vyera repurchase	455	—
Change in fair value of warrant liability	(292)	517
Change in fair value of convertible notes payable	3,017	(230)
Change in fair value of derivative liability	—	369
Gain on forgiveness of debt	—	(149)
Amortization of right-of-use asset	53	—
Net loss on extinguishment of debt	—	2,387
Amortization of debt discount	—	1,582
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	(2,247)	(2,894)
Accounts payable	1,933	(194)
Accrued expenses	3,522	1,806
Derivative liability	(1,174)	—
Lease liability	(51)	—
Licenses payable	800	(125)
Net cash used in operating activities	(61,604)	(48,995)
Cash flows (used in) provided by financing activities		
Payment of convertible note	(1,888)	(13,551)
Proceeds from issuance of common stock, net of issuance costs	—	97,957
Proceeds from issuance of common stock and convertible notes payable		20,203
Proceeds from exercise of warrants	—	7,252
Proceeds from issuance of common stock in at-the-market offering	457	—
Payment of at-the-market offering issuance costs	(273)	—
Proceeds from exercise of options	8	102
Proceeds from sales of common stock under ESPP	99	104
Net cash (used in) provided by financing activities	(1,597)	112,067
Net (decrease) increase in cash	(63,201)	63,072
Cash, beginning of period	78,734	15,662
Cash, end of period	$ 15,533	$ 78,734
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 11	$ 10
Cash paid for income taxes	$ —	$ —
Non-cash investing and financing activities:		
Reclass of warrant liabilities related to Series A warrants exercised for cash	$ —	$ 1,155
Right-of-use assets obtained in exchange for operating lease liabilities	$ 86	$ 75
Issuance of common stock for convertible notes	$ —	$ 69
Issuance of common stock for license payable	$ 840	$ —
At-the-market offering issuance costs, accrued but not paid	$ 32	$ —
Repurchase of common stock, accrued but not paid	$ 1,195	$ —
Issuance of common stock for settlement of debt	$ —	$ 1,377
Issuance of common stock for iX Biopharma license	$ —	$ 4,832
Extinguishment of beneficial conversion feature	$ —	$ 1,519

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

Seelos Therapeutics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

1. Organization and Summary of Significant Accounting Policies

Organization

Seelos Therapeutics, Inc. (together with its subsidiaries, the "Company") is a clinical-stage biopharmaceutical company focused on achieving efficient development of products that address significant unmet needs in Central Nervous System ("CNS") disorders and other rare disorders. The Company's lead programs are SLS-002 for the potential treatment of acute suicidal ideation and behavior in patients with major depressive disorder ("ASIB in MDD") and SLS-005 for the potential treatment of Amyotrophic Lateral Sclerosis ("ALS") and Spinocerebellar Ataxia ("SCA"). SLS-005 for the potential treatment of Sanfilippo Syndrome currently requires additional natural history data, which is being considered. Additionally, the Company is developing several preclinical programs, most of which have well-defined mechanisms of action, including: SLS-004, SLS-006 and SLS-007 for the potential treatment of Parkinson's Disease ("PD").

Basis of Presentation and Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of these consolidated 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 financial statements and the reported amounts of expenses during the reporting period. The most significant estimates in the Company's financial statements relate to the valuation of warrants, valuation of convertible notes payable, and the valuation of stock options. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected.

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use ("ROU") asset, operating lease liability, current and operating lease liability, long-term in the Company's condensed consolidated balance sheets. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liability represents its obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the commencement date based on the present value of the lease payments over the lease term. As the Company's leases do not provide an implicit rate, the Company uses an incremental borrowing rate based on the information available at the transition date and commencement date in determining the present value of lease payments. This is the rate the Company would have to pay if it borrowed on a collateralized basis over a similar term to each lease. The operating lease ROU asset also includes any lease payments made and excludes lease incentives. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Fair Value Option

As permitted under Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 825, Financial Instruments ("ASC 825"), the Company elected the fair value option to account for its November 2021 and December 2021 convertible notes (collectively, the "2021 Convertible Notes"). In accordance with ASC 825, the Company records these convertible notes at fair value with changes in fair value recorded in the Consolidated Statement of Operations and Comprehensive Loss. As a result of applying the fair value option, direct costs and fees related to the convertible notes were expensed as incurred and were not deferred.

Fair Value Measurements

The Company follows the accounting guidance in the FASB ASC Topic 820, Fair Value Measurements and Disclosures ("ASC 820"), for its fair value measurements of financial assets and liabilities measured at fair value on a recurring basis. Under this accounting guidance, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

The accounting guidance requires fair value measurements be classified and disclosed in one of the following three categories:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Observable inputs other than Level 1 prices, for similar assets or liabilities that are directly or indirectly observable in the marketplace.

Level 3: Unobservable inputs which are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

The carrying amounts of financial instruments such as accounts payable and accrued expenses approximate their related fair values due to the short-term nature of these instruments.

Research and Development

Research and development costs are expensed as incurred and include milestone and upfront payments for license arrangements, the cost of employee compensation and related expenses, as well as expenses for third parties who conduct research and development on the Company's behalf, pursuant to development and consulting agreements in place.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred income taxes are recorded for temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities. Deferred tax assets and liabilities reflect the tax rates expected to be in effect for the years in which the differences are expected to reverse. A valuation allowance is provided if it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company also follows the provisions of accounting for uncertainty in income taxes which prescribes a model for the recognition and measurement of a tax position taken or expected to be taken in a tax return, and provides guidance on derecognition, classification, interest and penalties, disclosure and transition.

Income (Loss) Per Common Share

Basic loss per share is computed by dividing net loss applicable to common stockholders by the weighted average number of shares of common stock outstanding during each period. Diluted loss per share includes the effect, if any, from the potential exercise or conversion of securities, such as convertible debt, warrants and stock options that would result in the issuance of incremental shares of common stock. In computing the basic and diluted net loss per share applicable to common stockholders, the weighted average number of shares remains the same for both calculations due to the fact that when a net loss exists, dilutive shares are not included in the calculation as the impact is anti-dilutive.

The following potentially dilutive securities outstanding for the year ended December 31, 2022 and 2021 have been excluded from the computation of diluted weighted average shares outstanding, as they would be anti-dilutive (in thousands):

	Year Ended December 31,	
	2022	2021
Outstanding stock options	10,400	7,306
Restricted stock units	—	2,400
Outstanding warrants	2,545	2,635
Convertible debt	3,397	3,704
	16,342	16,045

Stock-Based Compensation

The Company expenses stock-based compensation to employees, non-employees and board members over the requisite service period based on the estimated grant-date fair value of the awards and forfeitures rates. The Company accounts for forfeitures as they occur. Stock-based awards with graded-vesting schedules are recognized on a straight-line basis over the requisite service period for each separately vesting portion of the award. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model, and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. All stock-based compensation costs are recorded in general and administrative or research and development costs in the statements of operations based upon the underlying individual's role at the Company.

Performance share awards are initially valued based on the Company's closing stock price on the date of grant. The number of performance share awards that vest will be determined based on the achievement of specified performance milestones by the end of the performance period. Compensation expense for performance awards is recognized over the service period and will vary based on remeasurement during the performance period. If achievement of the performance milestone is not probable of achievement during the performance period, compensation expense is reversed.

Segment Information

The Company operates under one segment which develops pharmaceutical products.

Recent Accounting Pronouncements

In August 2020, the FASB issued Accounting Standards Update ("ASU") No. ASU 2020-06: Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity. This standard simplifies the accounting for convertible debt instruments by removing the separation models for convertible debt with a cash conversion feature, as well as convertible instruments with a beneficial conversion feature. As a result, entities will account for a convertible debt instrument wholly as debt, unless certain other conditions are met. The elimination of these models will reduce non-cash interest expense for entities that have issued a convertible instrument that was within the scope of those models before the adoption of ASU 2020-06. Additionally, ASU 2020-06 requires the application of the if-converted method for calculating diluted earnings per share, and precludes the use of the treasury stock method for certain debt instruments. The provisions of ASU 2020-06 are applicable for the Company beginning after January 1, 2024, with early adoption permitted no earlier than fiscal years beginning after December 15, 2020, and an entity should adopt the provisions at the beginning of its annual fiscal year. The Company has decided to early adopt the provisions of this ASU as of January 1, 2023 and the Company does not expect the adoption of ASU 2020-06 to have an impact on its consolidated financial statements and related disclosures.

In November 2021, the FASB issued ASU No. 2021-10, Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance, which amends disclosures to increase transparency of government assistance, including (i) the types of assistance, (ii) accounting for the assistance and (iii) the effect of the assistance on an entity's financial statements. The standard is effective for all business entities for annual periods beginning after December 15, 2021; therefore, it is effective for the Company's financial statements issued for the year ended December 31, 2022. While the adoption of this guidance did not have an impact on the Company's consolidated balance sheet, statement of operations or disclosures for the year ended December 31, 2022, the adoption of this guidance may require additional disclosures in the Company's financial statements in future periods if and when government assistance is received.

In June 2022, the FASB issued ASU No. 2022-03: ASC Subtopic 820 - Value Measurement of Equity Securities Subject to Contractual Sale Restrictions ("ASU 2022-03"). ASU 2022-03 amends ASC 820 to clarify that a contractual sales restriction is not considered in measuring an equity security at fair value and to introduce new disclosure requirements for equity securities subject to contractual sale restrictions that are measured at fair value. ASU 2022-03 applies to both holders and issuers of equity and equity-linked securities measured at fair value. The amendments in ASU 2022-03 are effective for the Company for fiscal years beginning after December 15, 2023, and the interim periods within those fiscal years. Early adoption is permitted for both interim and annual financial statements that have not yet been issued or made available for issuance. The Company is evaluating the impact of this pronouncement on its consolidated financial statements and related disclosures.

2. Liquidity and Going Concern

The accompanying consolidated financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to its ability to continue as a going concern.

The Company has limited revenues, has incurred operating losses since inception, and expects to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of December 31, 2022, the Company had $15.5 million in cash and an accumulated deficit of $214.7 million. The Company has historically funded its operations through the issuance of convertible notes (see Note 9), the sale of common stock (see Note 6) and the exercise of warrants (see Note 10).

The Company evaluated whether there are any conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year beyond the date of filing of this Annual Report on Form 10-K. Based on such evaluation and the Company's current plans (including the ongoing clinical programs for SLS-002, SLS-005 and other product candidates), which are subject to change, management believes that the Company's existing cash and cash equivalents as of December 31, 2022 are not sufficient to satisfy its operating cash needs for at least one year and that there is substantial doubt of its ability to continue as a going concern within one year beyond the date of filing of this Annual Report on Form 10-K.

The Company may raise substantial additional funds, and if it does so, it may do so through one or more of the following: issuance of additional debt or equity and/or the completion of a licensing or other commercial transaction for one or more of the Company's product candidates. If the Company is unable to maintain sufficient financial resources, its business, financial condition and results of operations will be materially and adversely affected. This could affect future development and business activities and potential future clinical studies and/or other future ventures. Failure to obtain additional equity or debt financing will have a material, adverse impact on the Company's business operations. There can be no assurance that the Company will be able to obtain the needed financing on acceptable terms or at all. Additionally, equity or convertible debt financings will likely have a dilutive effect on the holdings of the Company's existing stockholders.

3. Business Combination

On January 24, 2019, the Company (which was formerly known as "Apricus Biosciences, Inc.") ("Apricus") completed the business combination with Seelos Therapeutics, Inc., a Delaware corporation ("STI"), in accordance with the terms of the Agreement and Plan of Merger and Reorganization entered into on July 30, 2018 (the "Merger Agreement"). Pursuant to the Merger Agreement, (i) a former subsidiary of the Company merged with and into STI, with STI (renamed "Seelos Corporation") continuing as a wholly-owned subsidiary of the Company and the surviving corporation of the merger and (ii) the Company was renamed "Seelos Therapeutics, Inc." (the "Merger").

The Merger was accounted for as a reverse recapitalization under U.S. GAAP because the primary assets of Apricus were nominal at the close of the Merger. STI was determined to be the accounting acquirer based upon the terms of the Merger and other factors, including: (i) STI stockholders and other persons holding securities convertible, exercisable or exchangeable directly or indirectly for STI common stock owned the majority of the Company immediately following the effective time of the Merger, (ii) STI holds the majority (four of five) of board seats of the combined company, and (iii) STI's management holds all key positions in the management of the combined company.

STI acquired no tangible assets and assumed no employees or operation from Apricus. Additionally, Apricus' intellectual property was considered to have no value. The remaining Apricus liabilities had a fair value of approximately $300 thousand.

In connection with the Merger, the Company and STI entered into a Contingent Value Rights Agreement (the "CVR Agreement"). Pursuant to the CVR Agreement, Apricus stockholders received one contingent value right ("CVR") for each share of Apricus common stock held of record immediately prior to the closing of the Merger. Each CVR represents the right to receive payments based on Apricus' U.S. assets related to products in development, intended for the topical treatment of erectile dysfunction, which are known as Vitaros in certain countries outside of the United States (the "CVR Product Candidate"). In particular, CVR holders will be entitled to receive 90% of any cash payments (or the fair market value of any non-cash payments) exceeding $500,000 received, during a period of ten years from the closing of the Merger, based on the sale or out-licensing of Apricus' CVR Product Candidate intangible asset, including any milestone payments (the "Contingent Payments"), less reasonable transaction expenses. The Company is entitled to retain the first $500,000 and 10% of any Contingent Payments. The Company has agreed to pay up to $500,000 of such Contingent Payments that it receives to a third party pursuant to a settlement agreement between the Company and the third party. The Company assigned no value to the CVR Product Candidate intangible asset or the CVR in the acquisition accounting as of December 31, 2022.

4. Fair Value Measurement

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values. There were no other transfers between fair value measurement levels during the years ended December 31, 2022 and 2021 (in thousands):

	Fair Value Measurements as of December 31, 2022			
	(Level 1)	(Level 2)	(Level 3)	Total
Assets:				
Cash	$ 15,533	$ —	$ —	$ 15,533
Liabilities:				
Convertible notes payable, at fair value	$ —	$ —	$ 20,049	$ 20,049
Warrant liabilities, at fair value	—	—	132	132
	$ —	$ —	$ 20,181	$ 20,181

	Fair Value Measurements as of December 31, 2021			
	(Level 1)	(Level 2)	(Level 3)	Total
Assets:				
Cash	$ 78,734	$ —	$ —	$ 78,734
Liabilities:				
Convertible notes payable, at fair value	$ —	$ —	$ 18,920	$ 18,920
Derivative liability, at fair value	1,174	—	—	1,174
Warrant liabilities, at fair value	—	—	424	424
	$ 1,174	$ —	$ 19,344	$ 20,518

The Company measures the 2021 Convertible Notes and warrant liabilities at fair value based on significant inputs not observable in the market, which causes them to be classified as a Level 3 measurement within the fair value hierarchy. These valuations use assumptions and estimates the Company believes would be made by a market participant in making the same valuation. The Company assesses these assumptions and estimates on an on-going basis as additional data impacting the assumptions and estimates are obtained. Changes in the fair value of the 2021 Convertible Notes, derivative liability and warrant liabilities related to updated assumptions and estimates are recognized within the Consolidated Statements of Operations and Comprehensive Loss.

The fair value of the 2021 Convertible Notes and warrant liabilities may change significantly as additional data is obtained, impacting the Company's assumptions regarding probabilities of outcomes used to estimate the fair value of the liabilities. The estimates of fair value may not be indicative of the amounts that could be realized in a current market exchange. Accordingly, the use of different market assumptions and/or different valuation techniques may have a material effect on the estimated fair value amounts, and such changes could materially impact the Company's results of operations in future periods.

Derivative Liability

The derivative liability represented the fair value of the "Shortfall Amount" provision provided for in the license agreement with iX Biopharma Europe Limited. See Note 7.

At issuance, the fair value of the embedded derivative was estimated by using a Monte Carlo simulation model. As of December 31, 2021, the Company determined it was probable it would settle the Shortfall Amount in cash and estimated the fair value based on a probability weighted market approach. The Company paid the Shortfall Amount of $1.2 million in cash in January 2022.

2021 Convertible Notes

The 2021 Convertible Notes are valued using a Monte Carlo simulation model. The following assumptions were used in determining the fair value of the 2021 Convertible Notes as of December 31, 2022 and 2021:

	Year Ended December 31, 2022	Year Ended December 31, 2021
Risk-free interest rate	4.24 %	0.90% - 0.95 %
Volatility	105 %	113% - 114 %
Dividend yield	— %	— %
Contractual term (years)	1.9	3.0
Stock price	$ 0.68	$ 1.74 - 1.95

Warrant Liabilities

The common stock warrant liabilities were recorded at fair value using the Black-Scholes option pricing model. The following assumptions were used in determining the fair value of the warrant liabilities valued using the Black-Scholes option pricing model as of December 31, 2022 and 2021:

	Year Ended December 31, 2022	Year Ended December 31, 2021
Risk-free interest rate	4.71 %	0.75 %
Volatility	91.90 %	110.55 %
Dividend yield	— %	— %
Expected term (years)	1.07	2.07
Weighted-average fair value	$ 0.44	$ 1.40

The following table is a reconciliation for the common stock warrant liabilities and 2021 Convertible Notes measured at fair value using Level 3 unobservable inputs (in thousands):

	Warrant liabilities	Derivative liability	Convertible notes, at fair value
Balance as of December 31, 2020	$ 1,062	$ —	$ —
Warrant liability reclassified to stockholders' equity	(1,155)	—	—
Issuance of convertible notes, at fair value	—	—	19,150
Issuance of derivative liability	—	805	—
Change in fair value measurement of derivative liability	—	369	—
Change in fair value measurement of convertible notes	—	—	(230)
Change in fair value measurement of warrant liability	517	—	—
Balance as of December 31, 2021	$ 424	$ 1,174	$ 18,920
Settlement of derivative liability	—	(1,174)	—
Principal payment of convertible notes, at fair value	—	—	(1,888)
Change in fair value measurement of convertible notes	—	—	3,017
Change in fair value measurement of warrant liability	(292)	—	—
Balance as of December 31, 2022	$ 132	$ —	$ 20,049

For the years ended December 31, 2022 and 2021, the changes in fair value of the 2021 Convertible Notes, derivative liability and warrant liability primarily resulted from the volatility of the Company's common stock.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets are comprised of the following (in thousands):

	December 31,	
	2022	2021
Prepaid insurance	$ 104	$ 59
Prepaid clinical costs	6,837	4,481
Other	200	187
Prepaid expenses and other current assets	$ 7,141	$ 4,727

6. Common Stock Offerings

Open Market Sale Agreement

On May 12, 2022, the Company entered into an Open Market Sale Agreement℠ (the "Sale Agreement") with Jefferies LLC, as sales agent (the "Agent"), pursuant to which the Company may offer and sell shares of its common stock from time to time through the Agent (the "Offering"). The Company also filed a prospectus supplement, dated May 12, 2022, with the Securities and Exchange Commission (the "SEC") in connection with the Offering (the "Prospectus Supplement") under the Company's existing shelf Registration Statement on Form S-3, as amended (File No. 333-251356), which became effective on December 23, 2020 (the "Registration Statement"). Pursuant to the Prospectus Supplement, the Company may offer and sell shares having an aggregate offering price of up to $50.0 million. Under the terms of the Sale Agreement, the Agent is entitled to a commission at a fixed rate of 3.0% of the gross proceeds from each sale of shares under the Sale Agreement. The Company also reimburses the Agent for certain expenses incurred in connection with the Sale Agreement and agreed to provide indemnification and contribution to the Agent with respect to certain liabilities, including liabilities under the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended. During the year ended December 31, 2022, the Company sold an aggregate of 350,000 shares under the Sale Agreement, receiving net proceeds of $0.5 million. The Company currently intends to use any net proceeds from the Offering for general corporate purposes and to advance the development of its product candidates.

Public Offerings

On May 24, 2021, the Company completed an underwritten public offering, pursuant to which the Company sold 22,258,066 shares of its common stock, at a price to the public of $3.10 per share, which included the exercise in full by the underwriter of its option to purchase up to 2,903,226 additional shares of common stock. The net proceeds to the Company from the offering were approximately $64.5 million, after deducting underwriting discounts, commissions and other offering expenses. The Company used $7.3 million of the net proceeds from the offering for the partial repayment of certain outstanding convertible promissory notes.

On January 28, 2021, the Company completed an underwritten public offering, pursuant to which the Company sold 17,530,488 shares of its common stock, at a price to the public of $2.05 per share, which included the exercise in full by the underwriter of its option to purchase up to 2,286,585 additional shares of common stock. The net proceeds to the Company from the offering were approximately $33.5 million, after deducting underwriting discounts, commissions and other offering expenses. The Company used $3.8 million of the net proceeds from the offering for the partial repayment of certain outstanding convertible promissory notes.

Stock Purchase Agreement with iX Biopharma Europe Limited

On November 24, 2021, the Company entered in an exclusive license agreement and stock purchase agreement (the "iXBEL Stock Purchase Agreement") with iX Biopharma Europe Limited ("iXBEL"). As consideration for the license under the license agreement, the Company paid iXBEL an upfront fee of $9.0 million, comprised of $3.5 million in cash and 2,570,266 restricted shares of the Company's common stock. Pursuant to the iXBEL Stock Purchase Agreement, the Company agreed to reimburse iXBEL for the difference in value (the "Shortfall Amount") in the event the aggregate value of the 2,570,266 shares of the Company's common stock at the time of registration and issuance was less than $5.5 million. The initial fair value of this Shortfall Amount was $0.8 million and in January 2022, the Company settled the Shortfall Amount by the payment of $1.2 million in cash to iXBEL. The change in fair value of the Shortfall Amount is included in Change in fair value of derivative liability on the Consolidated Statement of Operations and Comprehensive Loss (see Note 4).

Pre-Merger Financing

On January 24, 2019, STI and Apricus closed a private placement transaction with certain accredited investors (the "Investors"), whereby, among other things, STI issued to investors shares of STI's common stock immediately prior to the Merger in a private placement transaction (the "Financing"), pursuant to a Securities Purchase Agreement, made and entered into as of October 16, 2018, by and among STI, Apricus and the investors, as amended (the "Purchase Agreement").

Pursuant to the Purchase Agreement, STI (i) issued and sold to the Investors an aggregate of 2,374,672 shares of STI's common stock, which converted pursuant to the exchange ratio in the Merger into the right to receive 1,829,407 shares of the Company's common stock and (ii) issued warrants representing the right to acquire 1,463,519 shares of common stock at a price per share of $4.15, subject to adjustment as provided therein (the "Series A Warrants"), most recently adjusted to a price per share of $0.2957 per share, and additional warrants initially representing the right to acquire no shares of common stock at a price per share of $0.001, subject to adjustment as provided therein (the "Series B Warrants" together with the Series A Warrants, the "Investor Warrants"), for aggregate gross proceeds of $18.0 million, or $16.5 million net of financing fees. The terms of the Investor Warrants included certain provisions that could result in adjustments to both the number of warrants issued and the exercise price of each warrant, which resulted in the warrants being classified as a liability upon issuance (see Note 10). The Investor Warrants were recorded at fair value of $21.5 million upon issuance and given the liability exceed the proceeds received, a loss of $5.0 million was recognized.

On March 7, 2019, the Company entered into Amendment Agreements (collectively, the "Amendment Agreements") with each Investor amending: (i) the Purchase Agreement, (ii) the Series A Warrants, and (iii) the Series B Warrants. The Amendment Agreements, among other things, fixed the aggregate number of shares of common stock issued and issuable pursuant to the Series A Warrants at 3,629,023 (none of which were exercised as of March 7, 2019). The terms of the Investor Warrants continue to include certain provisions that could result in a future adjustment to the exercise price of the Investor Warrants and accordingly, they continue to be classified as a liability after the Amendment Agreements.

At December 31, 2022, 0.3 million Series A Warrants remain unexercised.

7. License Agreements

Acquisition of License from Ligand Pharmaceuticals Incorporated

On September 21, 2016, the Company entered into a License Agreement (the "License Agreement") with Ligand Pharmaceuticals Incorporated ("Ligand"), Neurogen Corporation and CyDex Pharmaceuticals, Inc. (collectively, the "Licensors"), pursuant to which, among other things, the Licensors granted to the Company an exclusive, perpetual, irrevocable, worldwide, royalty-bearing, nontransferable right and license under (i) patents related to a product known as Aplindore, which is now known as SLS-006, acetaminophen (as it may have been or may be modified for use in a product to be administered by any method in any form including, without limitation injection and intravenously, the sole active pharmaceutical ingredient of which is acetaminophen), which is now known as SLS-012, an H3 receptor antagonist, which is now known as SLS-010, and either or both of the Licensors' two proprietary CRTh2 antagonists, which are now known collectively as SLS-008 (collectively, the "Licensed Products"), and (ii) copyrights, trade secrets, moral rights and all other intellectual and proprietary rights related thereto. The Company is obligated to use commercially reasonable efforts to (a) develop the Licensed Products, (b) obtain regulatory approval for the Licensed Products in the European Union (either in its entirety or including at least one of France, Germany or, if at the time the United Kingdom is a member of the European Union, the United Kingdom), the United Kingdom, if at the time the United Kingdom is not a member of the European Union, Japan or the People's Republic of China (each, a "Major Market") or the United States, and (c) commercialize the Licensed Products in each country where regulatory approval is obtained. The Company has the exclusive right and sole responsibility and decision-making authority to research and develop any Licensed Products and to conduct all clinical trials and non-clinical studies the Company believes appropriate to obtain regulatory approvals for commercialization of the Licensed Products. The Company also has the exclusive right and sole responsibility and decision-making authority to commercialize any of the Licensed Products.

In connection with the closing of the Merger, the Company issued 801,253 shares of common stock to Ligand and recognized research and development expense totaling approximately $2.2 million during the three months ended March 31, 2019 for the License Agreement.

The Company also agreed to pay to Ligand certain one-time, non-refundable regulatory milestone payments in connection with the Licensed Products, other than in connection with Aplindore for the indication of Parkinson's Disease ("PD") or Restless Leg Syndrome, consisting of (i) $750,000 upon submission of an application with the FDA or equivalent foreign body for a particular Licensed Product, (ii) $3.0 million upon FDA approval of an application for a particular Licensed Product, (iii) $1.125 million upon regulatory approval in a Major Market for a particular Licensed Product, and (iv) $1.125 million upon regulatory approval in a second Major Market for a particular Licensed Product.

The Company also agreed to pay to Ligand certain one-time, non-refundable regulatory milestone payments in connection with the Licensed Products in connection with Aplindore for the indication of PD or Restless Leg Syndrome, consisting of (i) $100,000 upon submission of an application with the FDA or equivalent foreign body for such a particular Licensed Product, (ii) $350,000 upon FDA approval of an application for such a particular Licensed Product, (iii) $125,000 upon regulatory approval in a Major Market for such a particular Licensed Product, and (iv) $125,000 upon regulatory approval in a second Major Market for such a particular Licensed Product.

The Company agreed to pay to Ligand certain one-time, non-refundable commercial milestone payments in connection with the Licensed Products, consisting of (i) $10.0 million upon the achievement of $1.0 billion of cumulative worldwide net sales of Licensed Products based upon Aplindore, (ii) $10.0 million upon the achievement of $1.0 billion of cumulative worldwide net sales of Licensed Products based upon an H3 receptor antagonist, (iii) $10.0 million upon the achievement of $1.0 billion of cumulative worldwide net sales of Licensed Products based upon acetaminophen (as it may have been or may be modified for use in a product to be administered by any method in any form including, without limitation injection and intravenously, the sole active pharmaceutical ingredient of which is acetaminophen), (iv) $10.0 million upon the achievement of $1.0 billion of cumulative worldwide net sales of Licensed Products based upon CRTh2 antagonists, (v) $20.0 million upon the achievement of $2.0 billion of cumulative worldwide net sales of Licensed Products based upon Aplindore, (vi) $20.0 million upon the achievement of $2.0 billion of cumulative worldwide net sales of Licensed Products based upon an H3 receptor antagonist, (vii) $20.0 million upon the achievement of $2.0 billion of cumulative worldwide net sales of Licensed Products based upon acetaminophen (as it may have been or may be modified for use in a product to be administered by any method in any form including, without limitation injection and intravenously, the sole active pharmaceutical ingredient of which is acetaminophen), and (viii) $20.0 million upon the achievement of $2.0 billion of cumulative worldwide net sales of Licensed Products based upon CRTh2 antagonists.

The Company will also pay to Ligand middle single-digit royalties on aggregate annual net sales of Licensed Products other than in connection with Aplindore for the indication of PD or Restless Leg Syndrome in a country where such Licensed Products are covered under a licensed patent and a tiered incremental royalty in the upper single digit to lower double digit range on aggregate annual net sales of Licensed Products in connection with Aplindore for the indication of PD or Restless Leg Syndrome in a country where such Licensed Products are covered under a licensed patent. Additionally, the Company will pay to Ligand low single digit royalties on aggregate annual net sales of Licensed Products other than in connection with Aplindore for the indication of PD or Restless Leg Syndrome in a country where such Licensed Products are not covered under a licensed patent and a tiered incremental royalty in the lower single digit to middle single digit range on aggregate annual net sales of Licensed Products in connection with Aplindore for the indication of PD or Restless Leg Syndrome in a country where such Licensed Products are not covered under a licensed patent.

The potential regulatory and commercial milestones are not yet considered probable, and no milestone payments have been accrued at December 31, 2022.

Acquisition of Assets from Phoenixus AG f/k/a Vyera Pharmaceuticals, AG and Turing Pharmaceuticals AG ("Vyera")

On April 8, 2022, Seelos Corporation ("STI"), a wholly-owned subsidiary of the Company, and Vyera, entered into an amendment (the "Amendment") to the Asset Purchase Agreement by and between STI and Vyera, dated March 6, 2018 (as amended by a first amendment thereto entered into on May 18, 2018, a second amendment thereto entered into on December 31, 2018, a third amendment thereto entered into on October 15, 2019 and a fourth amendment thereto entered into on February 15, 2021, the "Vyera Purchase Agreement"). Pursuant to the Vyera Purchase Agreement, STI acquired the assets and liabilities of Vyera related to a product candidate currently referred to as SLS-002 (intranasal ketamine) (the "Vyera Assets") and agreed, among other things, to make certain development and commercialization milestone payments and royalty payments related to the Vyera Assets (the "Milestone and Royalty Payment Obligations") and further agreed that in the event that the Company sold, directly or indirectly, all or substantially all of the Vyera Assets to a third party, then the Company would pay Vyera an amount equal to 4% of the net proceeds actually received by the Company as an upfront payment in such sale (the "Change of Control Payment Obligation").

Pursuant to the Vyera Purchase Agreement, as amended by the Amendment, STI agreed to (i) make a cash payment to Vyera in the aggregate amount of $4.0 million on or before April 8, 2022 (the "Cash Payment"); (ii) issue to Vyera on or before April 11, 2022 500,000 shares of the Company's common stock (the "Initial Shares"); (iii) issue to Vyera on or before July 11, 2022 an additional 500,000 shares of the Company's common stock (as adjusted for stock splits, stock dividends, combinations, recapitalizations and the like) (the "July 2022 Shares"); and (iv) issue to Vyera on or before January 11, 2023 an additional number of shares of the Company's common stock equal to $1.0 million divided by the volume weighted average closing price of the Company's common stock for the ten consecutive trading days ending on the fifth trading day prior to the applicable date of issuance of the shares of the Company's common stock (the "January 2023 Shares", and together with the Cash Payment, the Initial Shares and the July 2022 Shares, the "Final Payments"). In consideration for the Final Payments, all of STI's contingent payment obligations under the Vyera Purchase Agreement, including the Milestone and Royalty Payment Obligations and the Change of Control Payment Obligation, as well as all commercialization covenants of STI under the Vyera Purchase Agreement, will terminate in full upon the date that all of the Final Payments have been made.

On December 22, 2022, the Company entered into a Share Repurchase Agreement (the "Repurchase Agreement") with Vyera, pursuant to which the Company agreed to repurchase the 500,000 Initial Shares and the 500,000 July 2022 Shares previously issued to Vyera for an aggregate purchase price of $1.2 million in January 2023. Refer to Note 14 "Subsequent Events" below for a subsequent event related to the Vyera Purchase Agreement.

The Company paid the $4.0 million Cash Payment and issued the 500,000 Initial Shares to Vyera in April 2022. The Company issued the 500,000 July 2022 Shares to Vyera in July 2022, and subsequently agreed to repurchase the Initial Shares and the July 2022 Shares in January 2023 pursuant to the Repurchase Agreement on December 22, 2022. The Company recognized $5.8 million in research and development expense during the three months ended June 30, 2022 related to the Amendment, which consisted of the initial cash payment of $4.0 million and $0.8 million for the Initial Shares and the July 2022 Shares, which were measured at their grant-date fair value. The Company also recognized a liability of $1.0 million related to the January 2023 Shares within accrued licenses payable. The Company recognized a liability of $1.2 million related to the Repurchase Agreement, as well as $0.5 million in research and development expense for the premium paid for the repurchased shares.

The potential regulatory and commercial milestones are not yet considered probable, and no milestone payments have been accrued at December 31, 2022.

Acquisition of License from Stuart Weg, MD

On August 29, 2019, the Company entered into an amended and restated exclusive license agreement with Stuart Weg, M.D. (the "Weg License Agreement"), pursuant to which the Company was granted an exclusive worldwide license to certain intellectual property and regulatory materials related to SLS-002. Under the terms of the Weg License Agreement, the Company paid an upfront license fee of $75,000 upon execution of the agreement. The Company agreed to pay additional consideration to Dr. Weg as follows: (i) $0.1 million on January 2, 2020, (ii) $0.125 million on January 2, 2021, and (iii) in the event the FDA has not approved an NDA for a product containing ketamine in any dosage on or before December 31, 2021, $0.2 million on January 2, 2022. The Company paid the required $0.1 million on January 2, 2020, $0.125 million on January 2, 2021, and $0.2 million on January 3, 2022. As further consideration, the Company agreed to pay Dr. Weg certain milestone payments consisting of (i) $0.1 million and shares of common stock equal to $0.15 million divided by the closing sales price of the Company's common stock upon the issuance of the first patent directed to an anxiety indication, (ii) $0.5 million after the locking of the database and unblinding the data for the statistically significant readout of a Phase III trial of an intranasal racemic ketamine product that has been conducted for the submission under an NDA or equivalent seeking regulatory approval in the United States, the United Kingdom, France, Germany, Italy, Spain, China or Japan, or seeking regulatory approval from the EMA in the EU, for such product (the "Milestone Product"), (iii) $3.0 million upon FDA approval of an NDA for the Milestone Product, (iv) $2.0 million upon regulatory approval by the EMA for the Milestone Product, (v) $1.5 million upon regulatory approval in Japan for the Milestone Product; provided, however, that the maximum amount to be paid by the Company under milestones (i)-(v) will be $6.6 million. The Company will also pay to Dr. Weg a royalty percentage equal to 2.25% on the sale of each product containing ketamine in any dosage.

The potential regulatory and commercial milestones are not yet considered probable, and no milestone payments have been accrued at December 31, 2022.

Acquisition of Assets from Bioblast Pharma Ltd. ("Bioblast")

On February 15, 2019, the Company entered into an Asset Purchase Agreement (the "Bioblast Asset Purchase Agreement") with Bioblast. Pursuant to the Bioblast Asset Purchase Agreement, the Company acquired all of the assets of Bioblast relating to a therapeutic platform known as Trehalose (the "Bioblast Asset Purchase"). The Company paid to Bioblast $1.5 million in cash, and the Company paid to Bioblast an additional $2.0 million in February 2020. Accordingly, the Company recognized a $3.5 million charge to research and development expense during the year ended December 31, 2019. Under the terms of the Bioblast Asset Purchase Agreement, the Company agreed to pay additional consideration to Bioblast upon the achievement of certain milestones in the future, as follows: (i) within 15 days following the completion of the Company's first Phase II(b) clinical trial of Trehalose satisfying certain criteria, the Company will pay to Bioblast $8.5 million; and (ii) within 15 days following the approval for commercialization by the FDA or the Health Products and Food Branch of Health Canada of the first NDA or New Drug Submission, respectively, of Trehalose filed by the Company or its affiliates, the Company will pay to Bioblast $8.5 million. In addition, the Company agreed to pay Bioblast a cash royalty equal to 1% of the net sales of Trehalose. Under the terms of the Bioblast Asset Purchase, the Company assumed a collaborative agreement with Team Sanfilippo Foundation ("TSF"), a nonprofit medical research foundation founded by parents of children with Sanfilippo Syndrome. On July 15, 2019, TSF and the Company amended the agreement whereby the Company agreed to assume responsibility for a Phase II(b)/III clinical trial and TSF agreed to provide a grant of up to $1.5 million towards the funding of the trial.

The potential regulatory and commercial milestones are not yet considered probable, and no milestone payments have been accrued at December 31, 2022.

Acquisition of License from The Regents of the University of California

On March 7, 2019, the Company entered into an exclusive license agreement (the "UC Regents License Agreement") with The Regents of the University of California ("The UC Regents") pursuant to which the Company was granted an exclusive license to intellectual property owned by The UC Regents pertaining to a technology that was created by researchers at the University of California, Los Angeles ("UCLA"). Such technology relates to a family of rationally-designed peptide inhibitors that target the aggregation of alpha-synuclein ("α-synuclein"). The Company plans to study this initial approach in PD and will further evaluate the potential clinical approach in other disorders affecting the central nervous system ("CNS"). This program is now known as SLS-007. Upon entry into the UC Regents License Agreement, the Company paid to The UC Regents $0.1 million and recognized a $0.1 million charge to research and development expense during the year ended December 31, 2019. Under the terms of the UC Regents License Agreement, the Company agreed to pay additional consideration upon the achievement of certain milestones in the future, as follows: (i) within 90 days following the dosing of the first patient in a Phase I clinical trial, the Company will pay $50,000; (ii) within 90 days following dosing of the first patient in a Phase II clinical trial, the Company will pay $0.1 million; (iii) within 90 days following dosing of the first patient in a Phase III clinical trial, the Company will pay $0.3 million; (iv) within 90 days following the first commercial sales in the U.S., the Company will pay $1.0 million; (v) within 90 days following the first commercial sales in any European market, the Company will pay $1.0 million; and (vi) within 90 days following $250 million in cumulative worldwide net sales of a licensed product, the Company will pay $2.5 million. The Company is also obligated to pay a single digit royalty on sales of the product, if any. In addition, if the Company fails to achieve certain milestones within a specified timeframe, The UC Regents may terminate the agreement or reduce the Company's license to a nonexclusive license.

The potential regulatory and commercial milestones are not yet considered probable, and no milestone payments have been accrued at December 31, 2022.

Acquisition of License from Duke University

On June 27, 2019, the Company entered into an exclusive license agreement (the "Duke License Agreement") with Duke University pursuant to which the Company was granted an exclusive license to a gene therapy program targeting the regulation of the SNCA gene, which encodes α-synuclein expression. The Company plans to study this initial approach in PD and will further evaluate the potential clinical approach in other disorders affecting the CNS. This program is now known as SLS-004. Upon entry into the Duke License Agreement, the Company paid to Duke University $0.1 million and recognized $0.1 million charge to research and development expense during the year ended December 31, 2019. The Company agreed to pay additional consideration to Duke University upon the achievement of certain milestones in the future, as follows: (i) within 30 days following filing of an IND following the completion of preclinical studies including comprehensive validation of the platform, the Company will pay $0.1 million; (ii) within 30 days following dosing of the first patient in a Phase I clinical trial, the Company will pay $0.2 million; (iii) within 30 days following dosing of the first patient in a Phase II clinical trial, the Company will pay $0.5 million; (iv) within 30 days following dosing of the first patient in a Phase III clinical trial, the Company will pay $1.0 million; and (v) within 30 days following an NDA approval, the Company will pay $2.0 million. The Company is also obligated to pay a single digit royalty on sales of the product, if any. In addition, if the Company fails to achieve certain milestones within a specified timeframe, Duke University may terminate the agreement.

The potential regulatory and commercial milestones are not yet considered probable, and no milestone payments have been accrued at December 31, 2022.

Acquisition of License from iX Biopharma Europe Limited

On November 24, 2021, the Company entered into an exclusive license agreement (the "iX License Agreement") with iXBEL and the iXBEL Stock Purchase Agreement. Pursuant to the iX License Agreement, among other things, iXBEL granted the Company an exclusive, sublicensable, perpetual, worldwide (excluding certain jurisdictions identified in the iX License Agreement) and irrevocable right and license to certain of iXBEL's licensed patents, know-how, and technological information, including access to iXBEL's research, development and manufacturing capabilities, to enable the further development, manufacture, promotion and commercialization of WafermineTM and certain other existing and to be developed iXBEL wafer-based delivery technologies, in all cases for sublingual administration of ketamine. In addition, iXBEL will supply the Company with sufficient product for the potential treatment of 400 patients, with further supplied amounts to be determined by the parties. The Company granted iXBEL an exclusive license to exploit technology developed under the iX License Agreement outside of the licensed territory and to undertake limited, non-exclusive research and development activities in the territory. The Company further agreed not to undertake certain activities with respect to products competitive with those licensed under the iX License Agreement during the term of the iX License Agreement.

As consideration for the license under the iX License Agreement, the Company agreed to (i) pay iXBEL an upfront fee of $9.0 million, comprised of $3.5 million in cash and 2,570,266 restricted shares of its common stock; (ii) pay certain development, regulatory and commercial milestones, which, if achieved, aggregate to a total of $239.0 million; and (iii) pay royalty payments of ten percent on net sales, if any, as further set out in the iX License Agreement.

Pursuant to the iXBEL Stock Purchase Agreement, the Company also agreed to reimburse iXBEL for the Shortfall Amount in the event the aggregate value of the 2,570,266 shares of its common stock issued to iXBEL pursuant to the iXBEL Stock Purchase Agreement was less than $5.5 million. The Shortfall Amount could be paid in cash, additional shares of common stock or a combination of both. As of December 31, 2021, the Company calculated the Shortfall Amount to be $1.2 million. The Company paid the Shortfall Amount of $1.2 million to iXBEL in cash in January 2022.

The potential regulatory and commercial milestones are not yet considered probable, and no milestone payments have been accrued at December 31, 2022.

8. Accrued Expenses

Accrued expenses are comprised of the following (in thousands):

	December 31,	
	2022	2021
Professional fees	$ 278	$ 181
Personnel related	1,288	1,303
Outside research and development services	5,627	2,219
Other	89	25
Accrued expenses, net	$ 7,282	$ 3,728

9. Debt

Convertible Notes

November 2021 and December 2021 Convertible Notes and Private Placement

On November 23, 2021, the Company entered into a Securities Purchase Agreement (the "2021 Lind Securities Purchase Agreement") with Lind Global Asset Management V, LLC ("Lind V") pursuant to which, among other things, on November 23, 2021 (the "Closing Date"), the Company issued and sold to Lind V, in a private placement transaction (the "Private Placement"), in exchange for the payment by Lind V of $20.0 million, (i) a convertible promissory note (the "2021 Note") in an aggregate principal amount of $22.0 million (the "Principal Amount"), which will bear no interest until the first anniversary of the issuance of the 2021 Note and will thereafter bear interest at a rate of 5% per annum, and mature on November 23, 2024 (the "Maturity Date"), and (ii) 534,759 shares of Company common stock.

Commencing August 23, 2022, and from time to time and before the Maturity Date, Lind V has the option to convert any portion of the then-outstanding Principal Amount of the 2021 Note into shares of Common Stock at a price per share of $6.00, subject to adjustment for stock splits, reverse stock splits, stock dividends and similar transactions (the "Conversion Price"). Commencing August 23, 2022, the Company has the right to prepay, in whole or in part (exercisable by the Company at any time or from time to time prior to the Maturity Date), up to the full remaining Principal Amount of the 2021 Note with no penalty; however, if the Company exercises such prepayment right, Lind V will have the option to convert up to thirty-three and one-third percent (33 1/3%) of the amount that the Company elects to prepay at the Conversion Price.

Subject to certain exceptions, the Company will be required to direct proceeds from any subsequent debt financings (including subordinated debt, convertible debt or mandatorily redeemable preferred stock but other than purchase money debt or capital lease obligations or other indebtedness incurred in the ordinary course of business) to repay the 2021 Notes, unless waived by Lind V in advance.

Beginning on November 23, 2022, the 2021 Note amortizes in twenty-four monthly installments equal to the quotient of (i) the then-outstanding Principal Amount of the 2021 Note, divided by (ii) the number of months remaining until the Maturity Date. All amortization payments shall be payable, at the Company's sole option, in cash, shares of Common Stock or a combination of both. In addition, commencing on the last business day of the first month following November 23, 2022, the Company will pay, on a monthly basis, all interest that has accrued and remains unpaid on the then-outstanding Principal Amount of the 2021 Note. Any portion of an amortization payment or interest payment that is paid in shares of Common Stock shall be priced at 90% of the average of the five lowest daily volume weighted average prices of the Common Stock during the 20 trading days prior to the date of issuance of the shares. If, after the first amortization payment, the Company elects to make any amortization payments in cash, the Company shall pay a 5% premium on each cash payment. In conjunction with the 2021 Lind Securities Purchase Agreement and the 2021 Note, on the Closing Date, the Company and Lind V entered into a security agreement, which provides Lind V with a first priority lien on the Company's assets and properties.

On December 2, 2021, the Company entered into two separate securities purchase agreements with certain accredited investors on substantially the same terms as the 2021 Lind Securities Purchase Agreement, pursuant to which the Company sold, in private placement transactions, in exchange for the payment by the accredited investors of an aggregate of $201,534, (i) convertible promissory notes in an aggregate principal amount of $221,688, which will bear no interest and mature on December 2, 2024, and (ii) an aggregate of 5,388 shares of its common stock. These notes have substantially the same terms as the 2021 Note. On February 22, 2023, the December 2021 Notes were repaid in full.

During the year ended December 31, 2021, the Company received aggregate gross proceeds of $20.2 million from the convertible note offerings. The Company elected to account for these notes under the fair value option. At time of issuance, the Company recorded a liability of $19.2 million, which was determined to be the fair value at time of issuance. As of December 31, 2022 and 2021, the Company recognized a total convertible note liability of $20.0 million and $18.9 million, respectively. During the year ended December 31, 2022 and 2021, the Company recognized $3.0 million loss and $0.2 million gain on change in fair value of convertible notes, respectively.

During the year ended December 31, 2022, the Company made principal and interest payments of $1.9 million on the convertible notes. As of December 31, 2022, the principal and interest payment of the notes totaled $20.4 million.

Scheduled maturities with respect to the 2021 Convertible Notes are as follows (in thousands):

Year Ending December 31:		
2023	$	11,111
2024	$	9,259
2025	$	—
2026	$	—
2027	$	—
Total	$	**20,370**

December 2020 Convertible Note and Private Placement

On December 11, 2020, the Company entered into a Securities Purchase Agreement (the "2020 Lind Securities Purchase Agreement") with Lind Global Asset Management II, LLC (the "Investor") pursuant to which, among other things, on December 11, 2020, the Company issued and sold to the Investor, in a private placement transaction, in exchange for the payment by the Investor of $10,000,000, (1) a convertible promissory note (the "2020 Note") in an aggregate principal amount of $12,000,000 (the "Principal Amount"), which did not bear interest and was to mature on December 11, 2022 (the "Maturity Date"), and (2) 975,000 shares of the Company's common stock. At any time following June 11, 2021, and from time to time before the Maturity Date, the Investor had the option to convert any portion of the then-outstanding Principal Amount of the 2020 Note into shares of common stock at a price per share of $1.60, subject to adjustment for stock splits, reverse stock splits, stock dividends and similar transactions (the "Conversion Price"). Prior to June 11, 2021, the Company had the right to prepay up to sixty-six and two-thirds percent ($66^{2/3}\%$) of the then-outstanding Principal Amount of the 2020 Note with no penalty. Subject to certain exceptions, the Company was required to direct proceeds from any subsequent debt financings (including subordinated debt, convertible debt or mandatorily redeemable preferred stock but other than purchase money debt or capital lease obligations or other indebtedness incurred in the ordinary course of business) to repay the 2020 Note, unless waived by the Investor in advance. The 2020 Note began amortizing in June 2021 and was to amortize in eighteen monthly installments equal to the quotient of (i) the then-outstanding Principal Amount of the 2020 Note, divided by (ii) the number of months remaining until the Maturity Date. All amortization payments were to be payable solely in cash, plus a 2% premium. During the first half of 2021, the Company made certain repayments on the outstanding principal balance of the convertible notes. On June 14, 2021, the Company and the Investor entered into an Acknowledgment and Termination Agreement, pursuant to which the Company agreed to issue to the Investor an aggregate of 406,250 additional shares of its common stock (the "Lind Shares") and to pay the Investor the remaining principal amount of $790,804 (the "Final Payment") in full satisfaction of our remaining obligations to the Investor under the 2020 Note. The Company issued the Lind Shares and made the Final Payment to the Investor, and the 2020 Lind Securities Purchase Agreement and the 2020 Note terminated, effective June 15, 2021.

On December 17, 2020, the Company entered into three separate securities purchase agreements with certain accredited investors on substantially the same terms as the Lind Securities Purchase Agreement (the "December 17 SPAs"), pursuant to which the Company sold, in private placement transactions, in exchange for the payment by the accredited investors of an aggregate of $1,138,023, (1) convertible promissory notes (the "December 17 Notes") in an aggregate principal amount of $1,365,628, which did not bear interest and were to mature on December 17, 2022, and (2) an aggregate of 110,956 shares of its common stock. On December 18, 2020, the Company entered into an additional securities purchase agreement with an accredited investor on substantially the same terms as the Lind Securities Purchase Agreement (the "December 18 SPA" and, together with the December 17 SPAs, the "Subsequent Securities Purchase Agreements"), pursuant to which the Company sold, in a private placement transaction, in exchange for the payment by the accredited investor of $269,373, (1) a convertible promissory note in an aggregate principal amount of $323,247, which did not bear interest and was to mature on December 18, 2022 (the "December 18 Note" and, together with the December 17 Notes, the "Subsequent Notes"), and (2) 26,263 shares of the Company's common stock. The Subsequent Securities Purchase Agreements had substantially the same terms as the Lind Securities Purchase Agreement, and the Subsequent Notes had substantially the same terms as the 2020 Note. During the first half of 2021, the Company made certain repayments on the outstanding principal balance of the convertible notes. On July 7, 2021, the Company and the holder of the December 18 Note (the "December 18 Note Holder") entered into an Acknowledgement and Termination Agreement, pursuant to which: (i) the December 18 Note Holder agreed to return to the Company $42,777 in cash (the "Repayment") previously paid by the Company to the December 18 Note Holder as a payment against the Company's obligations under the December 18 Note, and (ii) the Company agreed to issue to the December 18 Note Holder an aggregate of 43,664 additional shares of its common stock (the "December 18 Note Shares") in full satisfaction of our remaining obligations to the December 18 Note Holder under the December 18 Note. The December 18 Note Holder paid the Company the Repayment and the Company issued the December Note Shares, and the December 18 SPA and the December 18 Note terminated, effective July 7, 2021.

The Company received aggregate net proceeds of $10.9 million from the convertible note offering, net of $0.5 million of issuance costs. The total gross proceeds were allocated to the convertible notes and common stock issued under the agreements based on their relative fair values. Due to the principal payments made during the year, the Company remeasured the beneficial conversion feature discount at each payment date and recorded a loss on extinguishment of debt of approximately $1.0 million during the year ended December 31, 2021 as well as a reduction in additional paid-in capital of $1.5 million as of December 31, 2021.

During the year ended December 31, 2021, the Company paid approximately $13.6 million in principal payments on the outstanding convertible notes and issued an aggregate of 475,315 shares of its common stock upon conversion of the convertible notes, and none of the 2020 convertible notes remain outstanding as of December 31, 2021.

PPP Loan

On May 4, 2020, the Company qualified for and received a loan pursuant to the Paycheck Protection Program, a program implemented by the U.S. Small Business Administration under the Coronavirus Aid, Relief, and Economic Security Act, from a qualified lender (the "PPP Lender"), for an aggregate principal amount of approximately $147,000 (the "PPP Loan"). The PPP Loan bore interest at a fixed rate of 1.0% per annum, with the first six months of interest deferred, had a term of two years, and was unsecured and guaranteed by the U.S. Small Business Administration. The principal amount of the PPP Loan was subject to forgiveness under the Paycheck Protection Program upon the Company's request to the extent that the PPP Loan proceeds were used to pay expenses permitted by the Paycheck Protection Program, including payroll costs, covered rent and mortgage obligations and covered utility payments incurred by the Company. The Company applied for and received full forgiveness of the PPP Loan with respect to these covered expenses and recorded a gain on forgiveness of debt during the year ended December 31, 2021.

10. Stockholders' Equity

Preferred Stock

The Company is authorized to issue 10,000,000 shares of preferred stock, par value $0.001. No shares of preferred stock were outstanding as of December 31, 2022 or 2021.

Common Stock

The Company has authorized 240,000,000 shares of common stock as of each of December 31, 2022 and 2021. Each share of common stock is entitled to one voting right. Common stock owners are entitled to dividends when funds are legally available and declared by the Board of Directors.

Warrants

September 2020 Warrants

On September 4, 2020, the Company entered into a securities purchase agreement with certain institutional investors, pursuant to which the Company issued and sold an aggregate of 8,865,000 shares of common stock in a registered direct offering and issued unregistered warrants to purchase up to 6,648,750 shares of common stock in a concurrent private placement (the "September 2020 Warrants"). The September 2020 Warrants are exercisable for 6,648,750 shares of common stock at an exercise price per share equal to $0.84. The September 2020 Warrants became exercisable beginning on March 9, 2021 and will expire on March 9, 2026.

During the year ended December 31, 2022, no September 2020 Warrants were exercised. As of December 31, 2022, September 2020 Warrants exercisable for 1.0 million shares of common stock remain outstanding at an exercise price of $0.84 per share.

August 2019 Warrants

On August 23, 2019, the Company entered into a securities purchase agreement with certain institutional investors pursuant to which the Company issued and sold an aggregate of 4,475,000 shares of common stock in a registered direct offering and issued warrants to purchase up to 2,237,500 shares of common stock in a concurrent private placement (the "August 2019 Warrants"). The August 2019 Warrants were initially exercisable for 2,237,500 shares of common stock at an exercise price per share equal to $1.78. The August 2019 Warrants became exercisable beginning on February 27, 2020 and will expire on August 28, 2023.

During the year ended December 31, 2022, no August 2019 Warrants were exercised. As of December 31, 2022, August 2019 Warrants exercisable for 900,000 shares of common stock remain outstanding at an exercise price of $1.78 per share.

Series A Warrants

The Series A Warrants were initially exercisable for 1,463,519 shares of common stock at an exercise price per share equal to $4.15, which was adjusted several times pursuant to the terms thereof to 3,629,023 shares of common stock at an exercise price per share equal to $0.2957 per share. The most recent adjustment to the exercise price (from $0.60 to $0.2957 per share) occurred during the three months ended September 30, 2020 as a result of the announcement of the offerings pursuant to the September 2020 Securities Purchase Agreement. The Series A Warrants were immediately exercisable upon issuance and will expire on January 31, 2024.

During the year ended December 31, 2022, no Series A Warrants were exercised. As of December 31, 2022, Series A Warrants exercisable for 0.3 million shares of common stock remain outstanding at an exercise price of $0.2957 per share.

A summary of warrant activity during the year ended December 31, 2022 is as follows (warrants in thousands):

	Warrants	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2021	2,635	$ 4.29	2.4
Issued	—	$ —	
Exercised	—	$ —	
Cancelled	(90)	$ 47.06	
Outstanding as of December 31, 2022	2,545	$ 2.78	1.7
Exercisable as of December 31, 2022	2,545	$ 2.78	1.7

The Series A Warrants were recognized as a liability at their fair value upon issuance. The warrant liability is remeasured to the then fair value prior to their exercise or at period end for warrants that are unexercised and the gain or loss recognized in earnings during the period.

11. Stock-Based Compensation

The Company has the Seelos Therapeutics, Inc. Amended and Restated 2012 Stock Long Term Incentive Plan (the "2012 Plan"), which provides for the issuance of incentive and non-incentive stock options, restricted and unrestricted stock awards, stock unit awards and stock appreciation rights. Options and restricted stock units granted generally vest over a period of one to four years and have a maximum term of ten years from the date of grant. The 2012 Plan provides that an additional number of shares will automatically be added annually to the shares authorized for issuance under the 2012 Plan on January 1st of each year commencing on January 1, 2020 and ending on (and including) January 1, 2029. The number of shares added each year will be equal to the lesser of (a) 4% of the number of shares of common stock issued and outstanding on a fully-diluted basis as of the close of business on the immediately preceding December 31, and (b) a number of shares of common stock set by the Company's board of directors on or prior to each such January 1. On January 1, 2022, in accordance with the foregoing, an aggregate of 4,713,637 shares of common stock were added to shares authorized for issuance under the 2012 Plan. As of December 31, 2022, an aggregate of 15,817,818 shares of common stock were authorized under the 2012 Plan, of which 5.4 million shares of common stock were available for future grants. No further awards may be issued under the Seelos Therapeutics, Inc. 2016 Equity Incentive Plan.

On May 15, 2020, the Company's stockholders approved the Company's 2020 Employee Stock Purchase Plan (the "ESPP"), whereby qualified employees are allowed to purchase limited amounts of the Company's common stock at the lesser of 85% of the market price at the beginning or end of the offering period. The stockholders have authorized an initial amount of 1.0 million shares for purchase by employees under the ESPP. The ESPP provides that an additional number of shares will automatically be added annually to the shares authorized for issuance under the ESPP on January 1st of each year commencing on January 1, 2021 and ending on (and including) January 1, 2030, which amount shall be equal to the lesser of (i) 1% of the number of shares of the Company's common stock issued and outstanding on the immediately preceding December 31, and (ii) a number of shares of common stock set by the Company's Board of Directors or the Compensation Committee of the Board of Directors (the "Compensation Committee") of the Company on or prior to each such January 1. On January 1, 2022, the Company added 1,055,004 shares for purchase by employees under the ESPP. During the year ended December 31, 2022, the Company sold 111,561 shares of common stock under the ESPP. The compensation costs are calculated as the fair value of the 15% discount from market price and were approximately $51,000 for the year ended December 31, 2022.

On July 28, 2019, the Compensation Committee adopted the Seelos Therapeutics, Inc. 2019 Inducement Plan (the "2019 Inducement Plan"), which became effective on August 12, 2019. The 2019 Inducement Plan provides for the grant of equity-based awards in the form of stock options, stock appreciation rights, restricted stock, unrestricted stock, stock units, including restricted stock units, performance units and cash awards, solely to prospective employees of the Company or an affiliate of the Company provided that certain criteria are met. Awards under the 2019 Inducement Plan may only be granted to an individual, as a material inducement to such individual to enter into employment with the Company, who (i) has not previously been an employee or director of the Company or (ii) is rehired following a bona fide period of non-employment with the Company. The maximum number of shares available for grant under the 2019 Inducement Plan is 1,000,000 shares of the Company's common stock, of which 646,465 shares of the Company's common stock are available for future issuance as of December 31, 2022. The 2019 Inducement Plan is administered by the Compensation Committee and expires on August 12, 2029.

Stock options

During the year ended December 31, 2022, the Company granted 660,605 incentive stock options and 2,299,395 non-qualified stock options to employees with a weighted average exercise price per share of $1.45 and a 10-year term, subject to the terms and conditions of the 2012 Plan or the 2019 Inducement Plan above. The stock options are subject to time vesting requirements. The stock options granted to employees vest 25% on the first anniversary of the grant and monthly thereafter over the next three years.

During the year ended December 31, 2022, the Company also granted 140,000 non-qualified stock options to non-employee directors with a weighted average exercise price per share of $1.56 and a 10-year term, subject to the terms and conditions of the 2012 Plan above. The stock options granted to non-employee directors vest monthly over the 12 months following the grant.

The fair value of stock option grants are estimated on the date of grant using the Black-Scholes option-pricing model. The Company was historically a private company and lacked sufficient company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on a weighted average blend of the historical volatility of a publicly traded set of peer companies, as well as its own historical volatility. Additionally, due to an insufficient history with respect to stock option activity and post-vesting cancellations, the expected term assumption for employee grants is based on a permitted simplified method, which is based on the vesting period and contractual term for each tranche of awards. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect for time periods approximately equal to the expected term of the award. Expected dividend yield is zero based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

During the year ended December 31, 2022, 6,250 stock options were exercised and no options were forfeited.

The following assumptions were used in determining the fair value of the stock options granted during the years ended December 31, 2022 and 2021:

	Year Ended December 31, 2022	Year Ended December 31, 2021
Risk-free interest rate	1.6%-3.4 %	0.5%-1.2 %
Volatility	111%-113 %	118%-125 %
Dividend yield	— %	— %
Expected term (years)	5-6	5-6
Weighted-average fair value	$ 1.22	$ 3.46

A summary of stock option activity during the year ended December 31, 2022 is as follows (in thousands, except exercise prices and years):

	Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Total Aggregate Intrinsic Value
Outstanding as of December 31, 2021	7,306	$ 2.60		
Granted	3,100	1.45		
Exercised	(6)	1.06		
Cancelled	—	—		
Outstanding as of December 31, 2022	10,400	$ 2.26	8.0	$ —
Vested and expected to vest as of December 31, 2022	10,400	$ 2.26	8.0	$ —
Exercisable as of December 31, 2022	4,545	$ 2.70	7.5	$ —

The intrinsic value of options exercised during the years ended December 31, 2022 and 2021 was $0.1 million and $0.3 million, respectively. As of December 31, 2022, unrecognized stock-option compensation expense of $7.5 million is expected to be realized over a weighted -average period of 2.2 years.

Performance Stock Award

During the year ended December 31, 2021, the Company's Board of Directors awarded a performance stock unit award to the Company's Chief Executive Officer for 2,400,000 shares of common stock, with a grant date fair value of $4.31 per unit. Vesting of this award was subject to the Company achieving certain performance criteria established at the grant date and the individual fulfilling a service condition (continued employment). As of December 31, 2021, all performance stock unit awards were unvested and three of the five performance conditions had been satisfied. The Company recognized stock-based compensation related to this award of $4.9 million during the fourth quarter of 2021, which was recorded in general and administrative expense. During the year ended December 31, 2022, the Company and its Chief Executive Officer entered into an agreement to cancel the performance stock unit award for no consideration. In connection with the cancellation of the award, no replacement awards were granted or authorized. At the time of cancellation, the Company recognized the remaining compensation expense of the three achieved milestones of $1.3 million. The two remaining milestones were not deemed probable of achievement at the time of cancellation, and no compensation cost related to these milestones was recognized.

The following table summarizes the total stock-based compensation expense resulting from share-based awards recorded in the Company's consolidated statements of operations (in thousands):

	Year Ended December 31,	
	2022	2021
Research and development	$ 932	$ 717
General and administrative	4,141	7,630
	$ 5,073	$ 8,347

13. Income Taxes

The Company has incurred net operating losses since inception. At December 31, 2022, the Company has available net operating loss carryforwards of approximately $104.2 million for federal income tax reporting purposes and approximately $90.8 million for state and local income tax reporting purposes. The net operating loss carryover of $104.2 million will be carried forward indefinitely. The state net operating loss carryover of $90.8 million will begin expiring in 2036.

Deferred tax assets consist of the following (in thousands):

	December 31,	
	2022	2021
Net operating tax loss carryforwards	$ 27,362	$ 30,751
Contingent payment obligations	461	407
Stock based compensation	1,559	3,208
R&E expenses	11,137	—
Intangible assets	8,577	16,970
Total deferred tax asset	49,096	51,336
Less valuation allowance	(49,096)	(51,336)
Net deferred tax asset	$ —	$ —

The federal and state net operating loss carryforwards, not subject to the annual limitation under Internal Revenue Code Section 382, resulted in a noncurrent deferred tax asset as of December 31, 2022 and 2021 of approximately $27.4 million and $30.8 million, respectively. In consideration of the Company's accumulated losses and the uncertainty of its ability to utilize this deferred tax asset in the future, the Company has recorded a full valuation allowance as of such dates.

Effective for tax years beginning after December 31, 2021, taxpayers are required to capitalize any expenses incurred that are considered incidental to research and experimentation ("R&E") activities under IRC Section 174. While taxpayers historically had the option of deducting these expenses under IRC Section 174, the December 2017 Tax Cuts and Jobs Act mandates capitalization and amortization of R&E expenses for tax years beginning after December 31, 2021. Expenses incurred in connection with R&E activities in the US must be amortized over a 5-year period if incurred, and R&E expenses incurred outside the US must be amortized over a 15-year period. R&E activities are broader in scope than qualified research activities considered under IRC Section 41 (relating to the research tax credit). For the year ended December 31, 2022, the Company performed an analysis based on available guidance and determined that it will continue to be in a loss position even after the required capitalization and amortization of its R&E expenses. The Company will continue to monitor this issue for future developments, but it does not expect R&E capitalization and amortization to require it to pay cash taxes now or in the near future.

The Company follows the provisions of income tax guidance which provides recognition criteria and a related measurement model for uncertain tax positions taken or expected to be taken in income tax returns. The guidance requires that a position taken or expected to be taken in a tax return be recognized in the financial statements when it is more likely than not that the position would be sustained upon examination by tax authorities. Tax positions that meet the more likely than not threshold are then measured using a probability weighted approach recognizing the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement. The Company's federal income tax returns for 2018 to 2022 are still open and subject to audit. In addition, net operating losses arising from prior years are also subject to examination at the time they are utilized in future years. Unrecognized tax benefits, if recognized, would have no effect on the Company's effective tax rate. The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. For the years ended December 31, 2022 and 2021, the Company has not recorded any interest or penalties related to income tax matters. The Company does not foresee any material changes to unrecognized tax benefits within the next twelve months.

The Company did not have any unrecognized tax benefits for the years ended December 31, 2022 and 2021.

The reconciliation of income taxes computed using the statutory United States income tax rate and the provision (benefit) for income taxes for the years ended December 31, 2022 and 2021, are as follows:

	Year Ended December 31,	
	2022	2021
Federal statutory tax rate	21.0 %	21.0 %
State and local taxes, net of federal benefit	— %	12.9 %
Permanent Items	(1.0)%	(1.1)%
Deferred rate changes	(12.9)%	2.3 %
Deferred true-up	(10.2)%	— %
Change in valuation allowance	3.1 %	(35.1)%
Income tax provision (benefit)	— %	— %

13. Commitments and Contingencies

Leases

In March 2019, the Company entered into a nine-month office space rental agreement for its headquarters in New York, New York expiring November 2019. In November 2019, the Company renewed this rental agreement for an additional twelve-months for a base rent of approximately $9,000 per month. In November 2020, the Company renewed this rental agreement for an additional twelve-months for a base rent of approximately $3,800 per month. In March 2021, the Company was notified that the counterparty's right to occupy the space at 300 Park Avenue, New York, NY was terminated, and the Company was required to vacate by March 26, 2021. The Company vacated the premises and has advised the counterparty that the counterparty is in breach of this rental agreement and therefore, the Company has no further obligations thereunder.

In March 2021, the Company entered into an eighteen-month office space rental agreement for its headquarters at 300 Park Avenue, New York, NY, which ended in September 2022. In October 2022, the Company entered into a new eighteen-month office space rental agreement for its existing space, which provides for a base rent starting at approximately $4,000 per month subject to periodic increases.

Under the new office space rental agreement in October 2022, in exchange for the new operating lease liability, the Company recognized a right-of-use asset of $86,000. As of December 31, 2022, the weighted-average remaining lease term of the operating lease was 1.3 years, and the weighted-average discount rate was 8.0%.

As of December 31, 2022, future minimum lease payments for the Company's operating lease with a non-cancelable term is as follows (in thousands):

	Operating Leases
Year Ended December 31, 2023	$ 62
Year Ended December 31, 2024	16
Total	78
Less present value discount	(5)
Operating lease liabilities	$ 73

For each of the years ended December 31, 2022 and 2021, operating lease expense totaled $0.1 million.

Contractual Commitments

The Company has entered into long-term agreements with certain manufacturers and suppliers that require it to make contractual payment to these organizations. The Company expects to enter into additional collaborative research, contract research, manufacturing, and supplier agreements in the future, which may require up-front payments and long-term commitments of cash.

Litigation

As of December 31, 2022, there was no material litigation against the Company.

14. Subsequent Events

On January 3, 2023, the Company paid $1.2 million in cash to Vyera under the Repurchase Agreement to repurchase the 500,000 Initial Shares and the 500,000 July 2022 Shares. See Note 7 for further discussion of the Vyera Asset Purchase Agreement.

On January 10, 2023, STI entered into Amendment No. 6 to the Vyera Purchase Agreement ("Amendment No. 6") with Vyera, pursuant to which, STI agreed to make two cash payments to Vyera in an aggregate amount of $500,000 each on January 31, 2023 and February 28, 2023, in lieu of issuing the January 2023 Shares to Vyera. The Company paid the $500,000 cash payments on each of January 31, 2023 and February 28, 2023 in satisfaction of all Final Payments under the Vyera Purchase Agreement. See Note 7 for further discussion of the Vyera Asset Purchase Agreement.

On January 26, 2023, the Company and The General Hospital Corporation, doing business as Massachusetts General Hospital ("MGH"), entered into a Consortium Agreement, whereby the parties will collaborate on an Expanded Access Protocol for SLS-005 in patients with ALS under an award from the National Institutes of Health, which was awarded to MGH in September 2022. Under the Consortium Agreement, the Company is a subrecipient of the award, with the Company's subaward totaling $2.9 million over a period ending August 31, 2025.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, communicated to our management to allow timely decisions regarding required disclosure, summarized and reported within the time periods specified in the SEC's rules and forms.

Under the supervision and with the participation of our management, including the Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), we conducted an evaluation of the effectiveness of our disclosure controls and procedures, as such term is defined under Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of December 31, 2022. Based on this evaluation, our CEO and CFO concluded that our disclosure controls and procedures were effective as of December 31, 2022 at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a 15(f). Our internal control over financial reporting is a process designed, under the supervision and, with the participation of our CEO who serves as our principal executive officer and principal financial officer, overseen by our Board of Directors and implemented by our management and other personnel, to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes 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 receipts and expenditures are being made only in accordance with authorizations of our management and 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 our financial statements.

Because of our inherent limitations, our internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Management performed an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2021 using criteria established in the *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on this assessment, management determined that, as of December 31, 2022, our internal control over financial reporting was effective. Because we are a smaller reporting company, KPMG, an independent registered public accounting firm, is not required to attest to or issue a report on the effectiveness of our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure system are met. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

There were no material changes to our internal control over financial reporting during the three months ended December 31, 2022.

ITEM 9B. OTHER INFORMATION

None.

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

Not applicable.

PART III.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference from the information contained in our Definitive Proxy Statement to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2022 in connection with the Annual Meeting of Stockholders to be held in 2023 (the "2023 Proxy Statement"). To the extent that we do not file the 2023 Proxy Statement by such date, we will file an amendment to this Annual Report on Form 10-K that includes the information required by this Item 10.

We have adopted a Code of Ethics for Officers (the "Code of Ethics") that is available at the Investors and Media/Corporate Governance Documents section of our website at www.seelostherapeutics.com.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the information contained in the 2023 Proxy Statement. The 2023 Proxy Statement will be filed within 120 days after the end of the fiscal year ended December 31, 2022. To the extent that we do not file the 2023 Proxy Statement by such date, we will file an amendment to this Annual Report on Form 10-K that includes the information required by this Item 11.

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

The information required by this item is incorporated by reference from the information contained in the 2023 Proxy Statement. The 2023 Proxy Statement will be filed within 120 days after the end of the fiscal year ended December 31, 2022. To the extent that we do not file the 2023 Proxy Statement by such date, we will file an amendment to this Annual Report on Form 10-K that includes the information required by this Item 12.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference from the information contained in the 2023 Proxy Statement. The 2023 Proxy Statement will be filed within 120 days after the end of the fiscal year ended December 31, 2022. To the extent that we do not file the 2023 Proxy Statement by such date, we will file an amendment to this Annual Report on Form 10-K that includes the information required by this Item 13.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference from the information contained in the 2023 Proxy Statement. The 2023 Proxy Statement will be filed within 120 days after the end of the fiscal year ended December 31, 2022. To the extent that we do not file the 2023 Proxy Statement by such date, we will file an amendment to this Annual Report on Form 10-K that includes the information required by this Item 14.

PART IV.

ITEM 15. EXHIBITS

(a) 1. Financial Statements:
The information required by this item is included in Item 8 of Part II of this Form 10-K.
2. Financial Statement Schedules
The information required by this item is included in Item 8 of Part II of this Form 10-K.
3. Exhibits
The following exhibits are incorporated by reference or filed as part of this report:

EXHIBITS NO.	DESCRIPTION
2.1+	Agreement and Plan of Merger and Reorganization, dated July 30, 2018, by and among the Company, Arch Merger Sub, Inc. and Seelos Therapeutics, Inc. (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 30, 2018).
2.2	Amendment No. 1 Agreement and Plan of Merger and Reorganization, dated October 16, 2018, by and among the Company, Arch Merger Sub, Inc. and Seelos Therapeutics, Inc. (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 17, 2018).
2.3	Amendment No. 2 Agreement and Plan of Merger and Reorganization, dated December 14, 2018, by and among the Company, Arch Merger Sub, Inc. and Seelos Therapeutics, Inc. (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 14, 2018).
2.4	Amendment No. 3 Agreement and Plan of Merger and Reorganization, dated January 16, 2019, by and among the Company, Arch Merger Sub, Inc. and Seelos Therapeutics, Inc. (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 16, 2019).
2.5+	Asset Purchase Agreement, dated February 15, 2019, by and between the Company and Bioblast Pharma Ltd. (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 19, 2019).
3.1	Amended and Restated Articles of Incorporation of the Company (incorporated herein by reference to Exhibit 2.1 to the Company's Registration Statement on Form 10-SB filed with the Securities and Exchange Commission on March 14, 1997).
3.2	Certificate of Amendment to Articles of Incorporation of the Company, dated June 22, 2000 (incorporated herein by reference to Exhibit 3.2 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2003).
3.3	Certificate of Amendment to Articles of Incorporation of the Company, dated June 14, 2005 (incorporated herein by reference to Exhibit 3.4 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 16, 2006).
3.4	Certificate of Amendment to Amended and Restated Articles of Incorporation of the Company, dated March 3, 2010 (incorporated herein by reference to Exhibit 3.6 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2010).

3.5	Certificate of Correction to Certificate of Amendment to Amended and Restated Articles of Incorporation of the Company, dated March 3, 2010 (incorporated herein by reference to Exhibit 3.7 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2010).
3.6	Certificate of Designation for Series D Junior-Participating Cumulative Preferred Stock (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-A filed with the Securities and Exchange Commission on March 24, 2011).
3.7	Certificate of Change filed with the Nevada Secretary of State (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 17, 2010).
3.8	Certificate of Amendment to Amended and Restated Articles of Incorporation of the Company, dated September 10, 2010 (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 10, 2010).
3.9	Certificate of Withdrawal of Series D Junior Participating Cumulative Preferred Stock, dated May 15, 2013 (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 16, 2013).
3.10	Certificate of Change filed with the Nevada Secretary of State (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 25, 2016).
3.11	Certificate of Amendment filed with the Nevada Secretary of State (incorporated herein by reference to Exhibit 3.10 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 2, 2017).
3.12	Certificate of Amendment filed with the Nevada Secretary of State (incorporated herein by reference to Exhibit 3.12 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 9, 2018).
3.13	Certificate of Amendment related to the Share Increase Amendment, filed January 23, 2019 (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 24, 2019 at 8:05 Eastern Time).
3.14	Certificate of Amendment related to the Name Change, filed January 23, 2019 (incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 24, 2019 at 8:05 Eastern Time).
3.15	Amended and Restated Bylaws, dated January 24, 2019 (incorporated herein by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 24, 2019 at 8:05 Eastern Time).
3.16	Certificate of Correction to Certificate of Amended and Restated Articles of Incorporation of the Company, dated March 25, 2020 (incorporated herein by reference to Exhibit 3.16 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 7, 2020)
3.17	Certificate of Amendment to the Amended and Restated Articles of Incorporation of Seelos Therapeutics, Inc., filed May 18, 2020 (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 19, 2020).
3.18	Certificate of Correction to Certificate of Amended and Restated Articles of Incorporation of the Company, filed May 20, 2020 (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 21, 2020).

3.19	Certificate of Amendment to the Amended and Restated Articles of Incorporation of the Company, filed May 21, 2021 (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 21, 2021).
4.1	Form of Common Stock Certificate (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 24, 2011).
4.2	Form of Warrant issued to the lenders under the Loan and Security Agreement, dated as of October 17, 2014, by and among the Company, NexMed (U.S.A.), Inc., NexMed Holdings, Inc. and Apricus Pharmaceuticals USA, Inc., as borrowers, Oxford Finance LLC, as collateral agent, and the lenders party thereto from time to time including Oxford Finance LLC and Silicon Valley Bank (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 20, 2014).
4.3	Form of Warrant (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 29, 2018).
4.4	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 29, 2018).
4.5	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 21, 2018).
4.6	Form of Wainwright Warrant (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 21, 2018).
4.7	Form of Investor Warrants (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 17, 2018).
4.8	Form of Series A Warrant, issued to investors on January 31, 2019 (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 6, 2019).
4.9	Form of Warrant, issued to investors on August 27, 2019 (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 27, 2019).
4.10	Form of Warrant, issued to investors on September 9, 2020 (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 9, 2020).
4.11	Form of Convertible Promissory Note due November 23, 2024 (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission at 7:27 a.m. Eastern Time on November 24, 2021).
4.12*	Description of Securities of Seelos Therapeutics, Inc.
4.13	Amendment to Convertible Promissory Note, by and between Seelos Therapeutics, Inc. and Lind Global Asset Management V, LLC, dated December 10, 2021 (incorporated by reference to Exhibit 4.22 to the Company's Form 10-K filed with the Securities and Exchange Commission on March 4, 2022).
4.14*	Amendment No. 2 to Convertible Promissory Note, by and between Seelos Therapeutics, Inc. and Lind Global Asset Management V, LLC, dated February 8, 2023.
10.1	Form of CVR Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 30, 2018).

10.2	Form of Indemnification Agreement for the Company's Directors and Officers (incorporated by reference to Exhibit 10.32 of the Company's Registration Statement on Form S-4 filed on August 31, 2018).
10.3†	License Agreement, dated September 21, 2016, by and among Seelos Therapeutics, Inc., Ligand Pharmaceuticals Incorporated, Neurogen Corporation and CyDex Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.33 of the Company's Registration Statement on Form S-4 filed on August 31, 2018).
10.4	Amendment to License Agreement, dated as of February 8, 2019, by and among Ligand Pharmaceuticals Incorporated, Neurogen Corporation, CyDex Pharmaceuticals, Inc., and Seelos Corporation (incorporated herein by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 17, 2020).
10.5	Indemnity Agreement, dated July 8, 2016, by and between Seelos Therapeutics, Inc. and Raj Mehra, Ph.D. (incorporated by reference to Exhibit 10.36 of the Company's Registration Statement on Form S-4 filed on August 31, 2018).
10.6#	Seelos Therapeutics, Inc. 2016 Equity Incentive Plan (incorporated by reference to Exhibit 10.39 of the Company's Registration Statement on Form S-4 filed on August 31, 2018).
10.7#	Form of Option Agreement under the Seelos Therapeutics, Inc. 2016 Equity Incentive Plan (incorporated by reference to Exhibit 10.40 of the Company's Registration Statement on Form S-4 filed on August 31, 2018).
10.8#*	Non-Employee Director Compensation Policy.
10.9#	Seelos Therapeutics, Inc. 2019 Inducement Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 14, 2019).
10.10#	Form of Stock Option Agreement under the Seelos Therapeutics, Inc. 2019 Inducement Plan (incorporated herein by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on August 15, 2019).
10.11^	Amended and Restated Exclusive License Agreement, dated August 29, 2019, by and between Seelos Therapeutics, Inc. and Stuart Weg, MD. (incorporated herein by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 7, 2019).
10.12#	Seelos Therapeutics, Inc. Amended and Restated 2012 Stock Long Term Incentive Plan, effective May 15, 2020 (incorporated herein by reference to Appendix B to the Registrant's Definitive Proxy Statement filed with the Securities and Exchange Commission on April 13, 2020).
10.13#	Form of Stock Option Grant Notice and Stock Option Agreement under the Company's 2012 Stock Long Term Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Form 10-Q filed with the Securities and Exchange Commission on August 11, 2014).
10.14#	Seelos Therapeutics, Inc. 2020 Employee Stock Purchase Plan (incorporated herein by reference to Appendix A to the Registrant's Definitive Proxy Statement filed with the Securities and Exchange Commission on April 13, 2020).
10.15 ^	Securities Purchase Agreement, dated as of November 23, 2021, by and between Seelos Therapeutics, Inc. and Lind Global Asset Management V, LLC. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission at 7:27 a.m. Eastern Time on November 24, 2021).

10.16	Security Agreement, dated as of November 23, 2021, by and between Seelos Therapeutics, Inc. and Lind Global Asset Management V, LLC. (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission at 7:27 a.m. Eastern Time on November 24, 2021).
10.17 ^ **	License Agreement, dated as of November 24, 2021, by and between Seelos Therapeutics, Inc. and iX Biopharma Europe Limited (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission at 8:20 a.m. Eastern Time on November 24, 2021).
10.18#	Amended and Restated Employment Agreement by and between Seelos Therapeutics, Inc. and Raj Mehra, Ph.D., dated as of January 10, 2022 (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 10, 2022).
10.19	Open Market Sale Agreement[SM], dated as of May 12, 2022, by and between Seelos Therapeutics, Inc. and Jefferies LLC (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission at 8:31 a.m. Eastern Time on May 12, 2022).
21.1*	Subsidiaries.
23.1*	Consent of KPMG, LLP, independent registered public accounting firm.
31.1*	Certification of Principal Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. (1)
32.2*	Certification of Principal Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. (1)
101.INS	XBRL Instance Document. (1)
101.SCH	XBRL Taxonomy Extension Schema. (1)
101.CAL	XBRL Taxonomy Extension Calculation Linkbase. (1)
101.DEF	XBRL Taxonomy Extension Definition Linkbase. (1)
101.LAB	XBRL Taxonomy Extension Label Linkbase. (1)
101.PRE	XBRL Taxonomy Extension Presentation Linkbase. (1)
104	Cover Page Interactive Data File (embedded wihin the Inline XBRL document)

(1) Furnished, not filed.

+ All schedules and exhibits to the agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities Exchange Commission upon request.

† Confidential treatment has been granted for portions of this exhibit. Those portions have been omitted and filed separately with the Securities and Exchange Commission.

* Filed herewith.

Management compensatory plan or arrangement

^ Non-material schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company hereby undertakes to furnish supplemental copies of any of the omitted schedules and exhibits upon request by the Securities and Exchange Commission.

** Certain identified information has been omitted pursuant to Item 601(b)(10) of Regulation S-K because such information is both (i) not material and (ii) is of the type that the Company treats as private or confidential. The Company hereby undertakes to furnish supplemental copies of the unredacted exhibit upon request by the Securities and Exchange Commission.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

Pursuant to the requirements 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.

Seelos Therapeutics, Inc.

Date: March 9, 2023

/s/ Raj Mehra, Ph.D.
Raj Mehra, Ph.D.
President and Chief Executive Officer

Date: March 9, 2023

/s/ Michael Golembiewski
Michael Golembiewski
Chief Financial Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Raj Mehra, Ph.D. his or her true and lawful attorneys-in-fact, each with full power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact or their substitute or substitutes may do or cause to be done by virtue hereof.

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 on the dates and the capacities indicated.

Signature	Title	Date
/s/ Raj Mehra, Ph.D. Raj Mehra, Ph.D.	President, Chief Executive Officer, and Chairman of the Board *(Principal Executive Officer)*	March 9, 2023
/s/ Michael Golembiewski Michael Golembiewski	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 9, 2023
/s/ Margaret Dalesandro Margaret Dalesandro	Director	March 9, 2023
/s/ Brian Lian, Ph.D. Brian Lian, Ph.D.	Director	March 9, 2023
/s/ Daniel J. O'Connor, J.D. Daniel J. O'Connor, J.D.	Director	March 9, 2023
/s/ Richard W. Pascoe Richard W. Pascoe	Director	March 9, 2023