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, 2019

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, 12th 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 is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

As of February 27, 2020, 36,505,044 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: $39.8 million based upon the closing sale price of the registrant's common stock of $2.19 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 2020 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, 2019.

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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) for Major Depressive Disorder (MDD) and Post-Traumatic Stress Disorder (PTSD)	Phase I	Phase I data anticipated in Q1 2020
SLS-005 IV Trehalose	Sanfilippo Syndrome	Phase II	Currently screening in US
SLS-004 Gene Therapy	Parkinson's Disease (PD)	Phase II	Preclinical studies to commence soon
SLS-006 Partial Dopamine Agonist	Parkinson's Disease (PD)	Phase II/III	Evaluating studies to advance into late stage trials
SLS-007 Peptide Inhibitor	Parkinson's Disease (PD)	Pre-IND	Preclinical data expected in 2H 2020
SLS-008 CRTh2 Antagonist	Pediatric Esophagitis, Asthma, Atopic Dermatitis	Pre-IND	Formulation work underway

Lead Programs

Our lead programs are currently SLS-002 for the potential treatment of suicidality in major depressive disorder ("MDD") and in post-traumatic stress disorder ("PTSD"), and SLS-005 for the potential treatment of Sanfilippo syndrome.

SLS-002 is intranasal racemic ketamine with two investigational new drug applications ("INDs"), for the treatment of acute suicidal ideation and behavior ("ASIB") in MDD and in PTSD. SLS-002 was originally derived from a Javelin Pharmaceuticals, Inc./Hospira, Inc. program with 16 clinical studies involving approximately 500 subjects. SLS-002 addresses an unmet need for an efficacious drug to treat suicidality in the U.S. 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. The clinical development program for SLS-002 includes two parallel healthy volunteer studies (Phase I), expected to be rapidly followed by pivotal registration studies after meeting with the FDA. We believe there is a large opportunity in the U.S. 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 more than 500,000 visits to emergency rooms for suicide attempts in 2013 in the U.S. alone. Experimental studies suggest ketamine has the potential to be a rapid, effective treatment for refractory depression and suicidality.

SLS-005 is IV Trehalose, a protein stabilizer that crosses the blood-brain-barrier, activates autophagy and lysosomal biogenesis. Based on the pre-clinical and in-vitro studies, there is a sound scientific rationale for developing Trehalose for the treatment of Sanfilippo syndrome. Trehalose is a low molecular weight disaccharide (.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 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 a good safety profile 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 two U.S. patents for parenteral administration of trehalose for patients with OPMD and SCA3, both of which are expected to expire in 2033. In addition, Orphan Drug Designation for OPMD and SCA3 has been secured in the U.S. 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.

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 PD, SLS-008, targeted at chronic inflammation in asthma and orphan indications such as pediatric esophagitis, SLS-010 in narcolepsy and related disorders and SLS-012, an injectable therapy for post-operative pain management.

Recent Developments

We recently announced interim data from our Phase I study of SLS-002. The study demonstrated that 60mg of SLS-002, when administered as a monotherapy and in combination with an oral antidepressant, was generally safe and well-tolerated. Further, on January 6, 2020, we announced the scheduling of a Type C meeting with the U.S. Food and Drug Administration ("FDA") in March 2020. In connection with this meeting, we will seek guidance for an adaptive Phase III trial of SLS-002 for Acute Suicidal Ideation and Behavior ("ASIB") in patients with MDD.

As a result of the scheduling 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 take advantage of the FDA's expedited programs for drug development and review.

Strategy and Ongoing Programs

SLS-002: The clinical development program for SLS-002 includes two parallel healthy volunteer studies (Phase I), expected to be rapidly followed by pivotal registration studies after meeting with the FDA. We have scheduled a Type C meeting with the FDA in March 2020 to seek guidance for an adaptive Phase III trial of SLS-002 for ASIB in patients with MDD.

SLS-005 will be studied in a clinical trial which is a combined Phase IIb/III, multicenter study designed to assess safety, tolerability and efficacy of IV Trehalose in Sanfilippo syndrome A and B patients. Outcome measures include functional outcomes, biomarkers, neuro-cognitive assessments and quality of life measurements. Additionally, we intend to conduct a second study that will include Sanfilippo syndrome C and D patients as well as Sanfilippo syndrome A and B patients who do not meet the criteria of inclusion for the Phase IIb/III study into a separate expanded patient access study.

SLS-004 is an all-in-one lentiviral vector, targeted for gene editing through DNA methylation within intron 1 of the SNCA gene responsible for expressing alpha-synuclein protein. SLS-004, when delivered to dopaminergic neurons derived from human induced pluripotent stem cells (hiPSCs) of a Parkinson's Disease ("PD") patient, modified the expression on alpha-synuclein and exhibited reversal of the disease-related cellular-phenotypes characteristics of the neurons.

The role of mutated SNCA in PD pathogenesis and the need to maintain the normal physiological levels of alpha-synuclein protein emphasize the so-far unmet need to develop new therapeutic strategies, such as SLS-004, targeting the regulatory mechanism of alpha-synuclein expression.

SLS-006 is a true partial dopamine agonist, originally developed by Wyeth Pharmaceuticals, Inc., with previous clinical studies on 340 subjects in various Phase I and Phase II studies. It is a potent D2/D3 agonist/antagonist that has shown promising efficacy with statistical significance in Phase II studies in early stage PD patients and an attractive safety profile. Moreover, it has also shown synergistic effect with reduced doses of L-DOPA. We are evaluating studies to advance the product candidate into late stage trials.

SLS-007 is a rationally designed peptide-based approach, targeting the NACore (nonamyloid component core) of alpha-synuclein to inhibit the protein from aggregation. Recent in-vitro and cell culture research have shown 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-alpha-synuclein peptidic inhibitors.

SLS-008 is an orally available antagonist for Chemoattractant Receptor-homologous molecules expressed on TH2 cells ("CRTh2"), targeted at chronic inflammation in asthma and a pediatric orphan indication. We have a "family" of compounds under our SLS-008 program. We intend to file an IND after completion of IND-enabling studies, which are currently in progress, in an undisclosed pediatric orphan indication where there is a high unmet need for an effective oral therapy.

Additionally, we are developing several preclinical programs, most of which have well-defined mechanisms of action, including:

- SLS-010, an oral histamine H3A receptor antagonist that shows promising activity in narcolepsy and related disorders; and
- SLS-012, an injectable therapy for post-operative pain management.

Merger

On January 24, 2019, Apricus Biosciences, Inc., a Nevada corporation ("Apricus"), 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 subsidiary of Apricus merged with and into STI, with STI (renamed as "Seelos Corporation") continuing as a wholly-owned subsidiary of Apricus and the surviving corporation of the merger and (ii) Apricus was renamed as "Seelos Therapeutics, Inc." (the "Merger"). Upon completion of the Merger, our business became primarily the business conducted by STI, which was a clinical-stage biopharmaceutical company focused on the development and commercialization of CNS therapeutics with known mechanisms of action in areas with a highly unmet medical need. Also, on January 23, 2019, in connection with, and prior to the completion of, the Merger, we effected a reverse stock split of our common stock at a ratio of 1-for-30 (the "Reverse Stock Split"). Our previous ticker symbol was "APRI". 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. See Note 1 to our consolidated financial statements for more information regarding 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, and we agreed to pay to Bioblast an additional $2.0 million in cash by the one-year anniversary of the Bioblast Closing. 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, a nonprofit medical research foundation founded by parents of children with Sanfilippo syndrome. TSF, upon approval by the FDA, plans to begin a Phase II(b)/III clinical trial in up to 24 patients with Sanfilippo syndrome, which is now known under the study name SLS-005. We will provide the clinical supply of Trehalose. The terms of the Bioblast Asset Purchase Agreement entitle us to access all clinical data from this trial. On July 15, 2019, we amended the agreement whereby we agreed to assume responsibility for the 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 Assets from Phoenixus AG f/k/a Vyera Pharmaceuticals, AG and Turing Pharmaceuticals AG ("Vyera")

On May 25, 2017, we entered into a non-binding term sheet to acquire TUR-002 (intranasal ketamine), which is now known as SLS-002, from Vyera. During the year ended December 31, 2017, we recorded $400,000 in research and development expenses related to the non-refundable but creditable payments to continue to negotiate exclusively with Vyera while we continued to identify financing terms with other parties to provide the necessary funding to purchase SLS-002.

On January 18, 2018, we entered into an Amendment to the May 25, 2017 term sheet for SLS-002 with Vyera. We paid $100,000 as a non-refundable but creditable payment to continue to negotiate exclusively with Vyera to purchase SLS-002.

On March 6, 2018, we entered into an Asset Purchase Agreement with Vyera, as amended by an amendment thereto entered into on May 18, 2018 and an amendment thereto entered into on December 31, 2018 (as amended, the "Vyera Agreement"), pursuant to which we agreed to acquire the assets (the "Vyera Assets"), and liabilities (the "Vyera Assumed Liabilities"), of Vyera related to a product candidate known as TUR-002 (intranasal ketamine), which is known as SLS-002. We are obligated to use commercially reasonable efforts to seek regulatory approval in the United States for and commercialize SLS-002. We agreed that if we receive regulatory approval to commence a Phase III clinical trial for SLS-002 and no third party has alleged any claim of conflict, infringement, invalidity or other violation of any rights of others with regard to the Vyera Assets, then we must commence a Phase III clinical trial for SLS-002 by June 30, 2020 (the "Phase III Obligation"), and if we failed to do so, the Vyera Agreement would terminate immediately and become null and void and all of the Vyera Assets and the Vyera Assumed Liabilities would automatically be returned to Vyera. As partial consideration for the Vyera Assets, we agreed to make a non-refundable milestone payment of $3.5 million upon dosing of the first patient in a Phase III clinical trial for SLS-002 (the "Dosing Milestone").

In the event that we sell, directly or indirectly, all or substantially all of the Vyera Assets to a third party, then we must pay Vyera an amount equal to 4% of the net proceeds actually received by us as an upfront payment in such sale.

As consideration for the Vyera Assets, we paid to Vyera a non-refundable cash payment of $150,000. As further consideration for the Vyera Assets, upon public announcement of the entry by Apricus and STI into the Merger Agreement, we paid to Vyera a non-refundable cash payment of $150,000. As further consideration for the Vyera Assets, we issued to Vyera 191,529 shares of common stock and paid Vyera a non-refundable cash payment $1,000,000. We agreed to pay to Vyera certain one-time, non-refundable milestone payments consisting of (i) $3.5 million upon dosing of the first patient in a Phase III clinical trial for SLS-002, (ii) $10.0 million upon approval by the FDA of an NDA, with respect to SLS-002, (iii) $5.0 million upon approval by the European Medicines Agency (the "EMA") of the foreign equivalent to an NDA with respect to SLS-002 in the EU (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 EU, the United Kingdom), the United Kingdom, if at the time the United Kingdom is not a member of the EU, Japan or the People's Republic of China (each, a "Major Market"), (iv) $2.5 million upon approval by the EMA of the foreign equivalent to an NDA with respect to SLS-002 in a second Major Market, (v) $5.0 million upon the achievement of $250.0 million in net sales of SLS-002, (vi) $10.0 million upon the achievement of $500.0 million in net sales of SLS-002, (vii) $15.0 million upon the achievement of $1.0 billion in net sales of SLS-002, (viii) $20.0 million upon the achievement of $1.5 billion in net sales of SLS-002, and (ix) $25.0 million upon the achievement of $2.0 billion in net sales of SLS-002. We will also pay to Vyera a royalty percentage in the mid-teens on aggregate annual net sales of SLS-002.

On October 15, 2019, we entered into an amendment (the "Amendment") to the Vyera Agreement with Vyera. Pursuant to the Amendment, we remain obligated to use our commercially reasonable efforts to seek regulatory approval in the United States for and commercialize SLS-002. However, the Amendment eliminates the Phase III Obligation. In addition, in replacement of our obligation to pay the Dosing Milestone, we agreed pursuant to the Amendment to (i) issue Vyera in January 2020 that number of registered shares of our common stock equal to $2,250,000 divided by the 30-day volume weighted average price of the common stock calculated prior to such issuance date, provided that we may elect, in our sole discretion, to pay Vyera cash (in whole or in part) in lieu of any shares of our common stock and (ii) make cash payments to Vyera in the amounts of $750,000, $750,000, $1.0 million and $1.0 million in October 2019, early January 2020, early April 2020 and early July 2020, respectively (each, a "Payment Obligation"). In event we fail to timely meet a Payment Obligation (subject to a cure period), Vyera has the right to require that all of the Vyera Assets and the Vyera Assumed Liabilities be returned to Vyera. On October 18, 2019, we made an additional cash payment of $750,000 to Vyera. On January 2, 2020, we entered into the Stock Purchase Agreement with Vyera, pursuant to which we issued 1,809,845 shares of our common stock as partial consideration for the Vyera Assets. On January 7, 2020, we made a cash payment of $750,000 to Vyera.

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. 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 alpha-synuclein (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 the completion of 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 alpha-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 to 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 are 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, the security holders of us 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 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 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 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.

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 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 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, we 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.

Legacy Pre-Merger Programs

As a result of the Merger, our going-forward operations will be primarily those of STI. Pursuant to the Merger, we retained certain assets and technologies that were Apricus' assets and technologies before the consummation of the Merger. Despite our expectation that our primary operations will be those of STI 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 "CRV 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 (the "Raynaud's Product Candidate").

The CVR Product Candidate is a topically-applied cream formulation of alprostadil, which is designed to dilate blood vessels. This combined with NexACT, our proprietary permeation enhancer, increases blood flow to the penis, causing an erection.

On February 15, 2018, the FDA, issued a complete response letter (a "CRL" and such CRL, the "2018 CRL") for the NDA for the CVR Product Candidate. A CRL is a communication from the FDA that informs companies that an application cannot be approved in its present form. In April 2018, we met with the FDA and confirmed that two new Phase III clinical efficacy trials would be necessary at a lower formulation concentration in order to potentially reach approval. We have initiated discussions with parties for the U.S. assets and rights related to the CVR Product Candidate to enable the CVR Product Candidate's continued development and potential approval in exchange for financial terms commensurate with a development stage asset.

On March 8, 2017, we entered into the Ferring Asset Purchase Agreement, pursuant to which we sold to Ferring our ex-US assets and rights related to products in development intended for the topical treatment of ED, which are known as Vitaros outside of the United States, for approximately $12.7 million, which consisted of an upfront payment of $11.5 million, approximately $0.7 million for the delivery of certain product-related inventory, and an aggregate of $0.5 million related to transition services.

In 2009, Warner Chilcott Company, Inc., now a subsidiary of Allergan, acquired the commercial rights to CVR Product Candidate in the United States. In September 2015, we entered into a license agreement and amendment to the original agreement with Warner Chilcott Company, Inc., granting us exclusive rights to develop and commercialize CVR Product Candidate in the United States. If the NDA is approved by the FDA, Allergan has a one-time opt-in right to assume all future commercialization activities for CVR Product Candidate in the United States. If Allergan exercises its opt-in right, we may receive up to a total of $25 million in upfront and potential launch milestone payments, plus a double-digit royalty on net sales of CVR Product Candidate. If Allergan elects not to exercise its opt-in right, we may commercialize the product, and in return, pay Allergan a high double-digit royalty on our net sales of the product.

In 2008, the FDA issued a CRL (the "2008 CRL") for the NDA for the CVR Product Candidate, identifying certain deficiencies in the application. Based on our subsequent interactions with the FDA and after completion of further drug-device engineering and other activities intended to address issues previously raised in the 2008 CRL, which included human factor testing as well as new non-clinical studies, we resubmitted the NDA for the CVR Product Candidate in August 2017. The 2018 CRL indicated that the modest treatment effect did not outweigh certain safety concerns specific to the 2.5% concentration of our permeation enhancer NexACT ("DDAIP.HCl") contained in the current formulation and identified deficiencies related to chemistry, manufacturing and controls ("CMC"). In April 2018, at our end-of-review meeting with the FDA, the FDA confirmed that we should develop a new CVR Product Candidate formulation that reduces the concentration of DDAIP.HCl from 2.5% to 0.5% in order to address the tumor promotion and partner transference safety concerns noted in the 2018 CRL. The FDA also confirmed that two new Phase III clinical efficacy trials with the reformulated product should be conducted prior to resubmitting the NDA and that the trials should include an assessment of the potential risk of enhanced sexually transmitted infections with the new formulation. In addition, the FDA requested certain pharmacokinetic assessments that we expect can be completed as part of the requested Phase III program and any additional clinical or commercial safety data generated prior to a resubmission. Lastly, the FDA stated that the CMC section in the resubmission will need to be updated with data generated during development of the new formulation.

The Raynaud's Product Candidate is intended for the treatment of Raynaud's Phenomenon associated with scleroderma (systemic sclerosis). Raynaud's Phenomenon is characterized by the constriction of the blood vessels in response to cold or stress of the hands and feet, resulting in reduced blood flow and the sensation of pain, which can be severe. The Raynaud's Product Candidate is a topically-applied cream formulation of alprostadil designed to dilate blood vessels, which is combined with our proprietary permeation enhancer NexACT, and applied on-demand to the affected extremities. The Raynaud's Product Candidate received authorization in May 2014 from the FDA to begin clinical studies. We reported results from our Phase IIa clinical trial of The Raynaud's Product Candidate for the treatment of Raynaud's Phenomenon secondary to scleroderma in September 2015. We are still assessing whether the safety concerns raised in the FDA's 2018 CRL specific to the 2.5% concentration of DDAIP.HCl contained in the current formulation of the CVR Product Candidate will affect the future development path of the Raynaud's Product Candidate since the underlying NexACT technology is utilized in both. We will not initiate any future clinical studies without a collaboration partner.

NexACT Drug Delivery Technology

The NexACT drug delivery technology consists of a proprietary small molecule permeation enhancer called Dodecyl 2-(N,N dimethylamino)-propionate ("DDAIP") that enables the rapid absorption of high concentrations of an active pharmaceutical ingredient directly at the target site, which is designed to enhance the delivery of an active drug to the patient. We are still assessing how the safety concerns specific to the 2.5% concentration of DDAIP.HCl contained in the current formulation of the CVR Product Candidate raised in the 2018 CRL may impact future development activities for other product candidates utilizing NexACT technology. The safety concerns raised were specific to the CVR Product Candidate for the treatment of ED and are

not necessarily transferable to other product candidates. As part of the Ferring Asset Purchase Agreement, we transferred the non-U.S. patents related to DDAIP and DDAIP in combination with alprostadil and received a perpetual, exclusive (even as to Ferring), fully transferable, fully sublicensable, royalty-free, fully paid-up license to such patents in certain fields other than sexual dysfunction.

Patent Portfolio

As of February 27, 2020, we owned or in-licensed approximately 37 issued patents that relate to our core programs, which will expire from 2020 through 2034, approximately. Also, as of that same date, we owned or in-licensed approximately 43 patent applications that relate to our core programs, which if ultimately issued would expire as late as approximately 2039, 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 27, 2020, 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. 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. We expect that the current presidential administration and U.S. Congress will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions 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 Trump'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 27, 2020, we had 6 full time employees 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.

Risks Related to the Company

We are a clinical-stage company, the company has 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, which has not changed as a result of the completion of the business combination between Apricus Biosciences, Inc., a Nevada corporation ("Apricus"), and 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, pursuant to which (i) a subsidiary of Apricus merged with and into STI, with STI (renamed as "Seelos Corporation") continuing as a wholly owned subsidiary of Apricus and the surviving corporation of the merger and (ii) Apricus was renamed as "Seelos Therapeutics, Inc." (the "Merger"). 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 $56.1 million from our inception through December 31, 2019.

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 U.S. Food and Drug Administration (the "FDA") the European Medicines Agency (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, SLS-005 and SLS-006 and our other earlier-stage assets, SLS-004, 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, 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, SLS-005 and SLS-006 and our earlier-stage assets, SLS-004, 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;
- 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.

Given our lack of current cash flow, we will 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.

Since we will be unable to generate sufficient, if any, cash flow to fund our operations for the foreseeable future, we will need to seek additional equity or debt financing to provide the capital required to maintain or expand our operations.

As of December 31, 2019, we had a cash balance of approximately $10.3 million. On February 13, 2020, we completed an underwritten public offering pursuant to which we sold 6,666,667 shares of our common stock at a price to the public of $0.75 per share. On February 19, 2020, we sold an additional 999,999 shares of our common stock at a price to the public of $0.75 per share pursuant to the full exercise of the underwriters' option to purchase additional shares to cover over-allotments. The net proceeds to us from the offering were approximately $5.0 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us. On March 16, 2020, we completed an additional underwritten public offering pursuant to which we sold 7,500,000 shares of our common stock at a price to the public of $0.60 per share. The net proceeds to us from the offering were approximately $3.9 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us.

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, 2019 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. As further discussed in the risk factor "As a result of our failure to timely file our Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, we are currently ineligible to file new short form registration statements on Form S-3, which may impair our ability to raise capital on terms favorable to us, in a timely manner or at all.", we will no longer be permitted to use our existing registration statements on Form S-3, including our shelf registration statement on Form S-3, as of the filing date of this Annual Report on Form 10-K for the fiscal year ended December 31, 2019. Absent a waiver of the Form S-3 eligibility requirements and assuming we continue to timely file our required reports under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the earliest we would regain the ability to use Form S-3 is June 1, 2020. At that time, 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. In addition, if, and/or when, we regain eligibility to use our shelf registration statement on Form S-3, under current SEC regulations, in the event that the aggregate market value of our common stock held by non-affiliates ("public float") is less than $75.0 million, the amount we can raise through primary public offerings of securities, including sales under an Equity Distribution Agreement with Piper Jaffray & Co. (the "Equity Distribution Agreement") (if we determine to un-suspend the continuous offering thereunder), in any twelve-month period using shelf registration statements is limited to an aggregate of one-third of our public float. SEC regulations permit us to use the highest closing sales price of our common stock (or the average of the last bid and last ask prices of our common stock) on any day within 60 days of sales under the shelf registration statement. As of February 27, 2020, our public float was approximately $51.9 million based on 36.5 million shares of our common stock outstanding at a price of $1.56 per share, which was the closing sale price of our common stock on January 8, 2020. Our public float was less than $75.0 million as of February 27, 2020, therefore we are limited to an aggregate of one-third of our public float in the amount we could raise through primary public offerings of securities in any twelve-month period using shelf registration statements. Although we would still maintain the ability to raise funds through other means, such as through the filing of a registration statement on Form S-1 or in private placements, the rules and regulations of the SEC or any other regulatory agencies may restrict our ability to conduct certain types of financing activities, or may affect the timing of and amounts we can raise by undertaking such activities.

There can be no assurance that we will be able to raise sufficient additional capital on acceptable terms or at all. 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. Our inability to raise capital when needed would 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.

As a result of our failure to timely file our Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, we are currently ineligible to file new short form registration statements on Form S-3, which may impair our ability to raise capital on terms favorable to us, in a timely manner or at all.

Form S-3 permits eligible issuers to conduct registered offerings using a short form registration statement that allows the issuer to incorporate by reference its past and future filings and reports made under the Exchange Act. In addition, Form S-3 enables eligible issuers to conduct primary offerings "off the shelf" under Rule 415 of the Securities Act of 1933, as amended (the "Securities Act"). The shelf registration process, combined with the ability to forward incorporate information, allows issuers to avoid delays and interruptions in the offering process and to access the capital markets in a more expeditions and efficient manner than raising capital in a standard registered offering pursuant to a Registration Statement on Form S-1. The ability to register securities for resale may also be limited as a result of the loss of Form S-3 eligibility.

The significant changes to the results of operations and presentation of financial statements required to account for the Merger in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, and the significant turnover in key personnel in connection with the Merger combined to cause a delay in the completion of our financial statements as of, and for the period ended, March 31, 2019. In particular, because the warrants issued in the Merger were subsequently amended on multiple occasions in the first quarter, and a number of warrants were exercised during the quarter, we were required to remeasure the value of the warrants at multiple points during the quarter. This, in turn, resulted in a non-cash modification of the fair value of the warrants during the quarter. Accordingly, we were unable to complete the compilation, analysis and review of information required to be included in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2019 until May 21, 2019, one day after the deadline for such filing.

As a result of our failure to timely file our Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, we are currently ineligible to file new short form registration statements on Form S-3 and, absent a waiver of the Form S-3 eligibility requirements, we will no longer be permitted to use our existing registration statements on Form S-3 as of the filing date of this Annual Report on Form 10-K for the fiscal year ended December 31, 2019. As a consequence, absent a waiver of the Form S-3 eligibility requirements, we are not permitted to sell all of the amount of common stock we could otherwise sell, subject to the limits of General Instruction I.B.6 of Form S-3, under the Equity Distribution Agreement (if we determine to un-suspend the continuous offering thereunder), which could adversely affect our ability to run our operations and progress our product development programs. We will not be permitted to conduct an "at the market offering" pursuant to the Equity Distribution Agreement absent an effective primary registration statement on Form S-3.

Our inability to use Form S-3 may significantly impair our ability to raise necessary capital to run our operations and progress our product development programs. If we seek to access the capital markets through a registered offering during the period of time that we are unable to use Form S-3, we may be required to publicly disclose the proposed offering and the material terms thereof before the offering commences, we may experience delays in the offering process due to SEC review of a Form S-1 registration statement and we may incur increased offering and transaction costs and other considerations. Disclosing a public offering prior to the formal commencement of an offering may result in downward pressure on our stock price. If we are unable to raise capital through a registered offering, we would be required to conduct our equity financing transactions on a private

placement basis, which may be subject to pricing, size and other limitations imposed under the rules of The Nasdaq Stock Market LLC, or seek other sources of capital.

Absent a waiver of the Form S-3 eligibility requirements and assuming we continue to timely file our required Exchange Act reports, the earliest we would regain the ability to use Form S-3 is June 1, 2020.

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.

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.

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.

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; or
- the FDA, the EMA or a comparable foreign authority may change its approval policies or adopt new regulations.
- Our inability to obtain these approvals would prevent us from commercializing our product candidates.

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, the 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, 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.

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 plan to seek orphan drug designation from the FDA for SLS-005 for Sanfilippo syndrome and 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.

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, such as the recent coronavirus disease 2019 (COVID-19), 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.

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" ("AMP"), 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 recent public announcements by members of the U.S. Congress, President Trump and his administration regarding their plans to repeal and replace the PPACA and Medicare. For example, on December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act of 2017, 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 Europe, the United Kingdom withdrew from the European Union on January 31, 2020. A significant portion of the regulatory framework in the United Kingdom is derived from the regulations of the European Union, and European Union pharmaceutical law remains applicable to the United Kingdom until December 31, 2020. We cannot predict what consequences the withdrawal of the United Kingdom from the European Union might have on the regulatory frameworks of the United Kingdom or the European Union, or on our future operations, if any, in these jurisdictions.

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 27, 2020, we have 6 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. 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. 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. 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 lack of 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 officer does not have experience in managing and operating a public company, which could have an adverse effect on his 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 officer does not have experience 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 disaster, such as an earthquake, hurricane, flood or fire, 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.

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, 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") and our license agreement with Duke University (the "Duke License Agreement", together with the Ligand License Agreement and the UC Regents 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, the licensor has the right to terminate the Duke License Agreement 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 prevents or impairs 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 their 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 issue shares, 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 licensors under the License Agreement up to an aggregate of approximately $135 million in development, regulatory and sales milestones. We will also be required to pay royalties on future worldwide net product sales. In addition pursuant to the asset purchase agreement, as amended (the "Vyera APA"), with Phoenixus AG f/k/a Vyera Pharmaceuticals AG and Turing Pharmaceuticals AG ("Vyera") we will be required to make cash payments to Vyera in the amounts of $1.0 million and $1.0 million in April 2020 and July 2020, respectively, and we will also be required to pay royalties to Vyera on net sales of SLS-002. We will also be required to pay $2.0 million in cash

and up to an aggregate of approximately $17 million in development and regulatory milestones and royalties on 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. Additionally, if we fail to timely make the mandatory cash payments under the Vyera APA (subject to a cure period), Vyera has the right to require that all of the assets we purchased from Vyera and the liabilities we assumed from Vyera be returned, which would result in a return of our SLS-002 program to Vyera and our inability to further develop such program. Pursuant to the amended and restated license agreement with Stuart Weg, M.D., we will be required to make cash payments to Dr. Weg in the amount of $0.125 million in January 2021 and, if certain conditions are not met, we will be required to make an additional cash payment of $0.2 million in January 2022.

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.

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.

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 arise 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 is expected to be volatile.

The trading price of our common stock is likely to be volatile. 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;
- public health crises, pandemics and epidemics, such as the recent coronavirus disease 2019 (COVID-19);
- sales of our common stock by us or our stockholders in the future; and
- 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 November 6, 2019, we were notified that, based on the previous thirty consecutive business days, our common stock no longer met the minimum $1.00 bid price per share requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2) and at that time, we were provided 180 calendar days, or until May 4, 2020, to regain compliance. On December 26, 2019, we were notified by Nasdaq that for more than the last ten consecutive business days, from December 6, 2019 through December 24, 2019, the closing bid price of our common stock had been at $1.00 per share or greater and that we had regained compliance with Nasdaq Listing Rule 5550(a)(2). While we have regained compliance with the Nasdaq Capital Market's continued listing requirements, there is no guarantee that we will remain in compliance with such listing requirements in the future.

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 management owns a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of February 27, 2020, Dr. Mehra, our sole executive officer and a director, owns approximately 8.8% of our outstanding common stock. Therefore, Dr. Mehra will have the ability to influence us through this ownership position.

This significant concentration of stock ownership may adversely affect the trading price for our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. As a result, Dr. Mehra could significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. Dr. Mehra may be able to determine all matters requiring stockholder approval. The interests of these stockholders may not always coincide with our interests or the interests of other stockholders. This may also prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interests as one of our stockholders and he may act in a manner that advances his best interests and not

necessarily those of other stockholders, including seeking a premium value for his common stock, and might affect the prevailing market price for our common stock.

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 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.

We will incur significant costs as a result of operating as a public company, our management has limited experience managing 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.

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.

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 February 27, 2020, we have outstanding warrants to purchase an aggregate of approximately 3.6 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.

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 agreed to issue 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 March 16, 2020, the Financing Warrants were exercisable for approximately 0.9 million shares of our common stock at an exercise price of $0.60 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 charter 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, 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 shareholder, unless (with certain exceptions) the "combination" or the transaction by which the person became an interested shareholder 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 shareholder. Generally, an "interested stockholder" is a person who, together with affiliates and associates, beneficially owns or within two years prior to becoming an "interested shareholder" 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 pre-Merger net operating loss carryforwards and certain other tax attributes may be subject to limitations. The pre-Merger net operating loss carryforwards and certain other tax attributes of us may also be subject to limitations as a result of ownership changes resulting from the Merger.

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 and/or the closing of the Merger. 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 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 does not anticipate it 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.

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 27, 2020, the last reported sales price for our common stock on the Nasdaq Capital Market was $0.84 per share, and we had approximately 100 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.

Equity Compensation Plan

The following table gives information as of December 31, 2019 about shares of our common stock that may be issued upon the exercise of options under our existing equity compensation plans:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)(1)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)(2)
Equity compensation plans approved by security holders(3)(4)	393,582	$ 11.72	-
Equity compensation plans not approved by security holders(5)	128,101	$ 1.37	871,899
Total	521,683	$ 9.18	871,899

(1) Consists of the weighted average exercise price of outstanding options as of December 31, 2019.

(2) Consists entirely of shares of common stock that remain available for future issuance under the Seelos Therapeutics, Inc. 2019 Inducement Plan (the "Inducement Plan") and the Amended and Restated Apricus 2012 Stock Long Term Incentive Plan (the "2012 Plan") as of December 31, 2019.

(3) Consists of options outstanding as of December 31, 2019 under 2012 Plan and the NexMed, Inc. 2006 Stock Incentive Plan.

(4) The number of shares of our common stock available for issuance under the 2012 Plan will increase automatically on January 1st of each year, beginning January 1, 2020 and ending on (and including) January 1, 2029 by the lesser of (a) 4% of the number of shares of our 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 our board of directors on or prior to each such January 1.

(5) Consists of the Inducement Plan and the Seelos Therapeutics, Inc. 2016 Equity Incentive Plan (the "2016 Plan"). See Note 8 to our consolidated financial statements for more information regarding the 2019 Plan and the 2016 Plan.

Unregistered Sales of Equity Securities and Use of Proceeds

None.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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

Overview

We are a clinical-stage biopharmaceutical company focused on developing novel technologies and therapeutics for the treatment of central nervous system, respiratory and other disorders.

Merger

On January 24, 2019, Apricus completed the Merger with STI. Upon completion of the Merger, we changed our name to Seelos Therapeutics, Inc. and focused on the development and commercialization of CNS therapeutics with known mechanisms of action in areas with a highly unmet medical need. Also, on January 23, 2019, in connection with, and prior to the completion of, the Merger, we effected the Reverse Stock Split. 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. Our previous ticker symbol was "APRI". See Note 1 to our consolidated financial statements for more information regarding the Merger.

Pipeline

We are planning on developing our clinical and regulatory strategy with our internal research and development team with a view toward prioritizing market introduction as quickly as possible. Our lead programs are currently SLS-002 for the potential treatment of suicidality in MDD and in PTSD, and SLS-005 for the potential treatment of Sanfilippo syndrome.

SLS-002 is intranasal racemic ketamine with two INDs for the treatment of ASIB in MDD and PTSD. SLS-002 was originally derived from a Javelin Pharmaceuticals, Inc./Hospira, Inc. program with 16 clinical studies involving approximately 500 subjects. SLS-002 addresses an unmet need for an efficacious drug to treat suicidality in the U.S. 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. The clinical development program for SLS-002 includes two parallel healthy volunteer studies (Phase I), expected to be rapidly followed by pivotal registration studies after meeting with the FDA. We believe there is a large opportunity in the U.S. 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 more than 500,000 visits to emergency rooms for suicide attempts in 2013 in the U.S. alone. Experimental studies suggest ketamine has the potential to be a rapid, effective treatment for refractory depression and suicidality.

We recently announced interim data from our Phase I study of SLS-002. The study demonstrated that 60mg of SLS-002, when administered as a monotherapy and in combination with an oral antidepressant, was generally safe and well-tolerated. Further, on January 6, 2020, we announced the scheduling of a Type C meeting with the FDA in March 2020. In connection with this meeting, we will seek guidance for an adaptive Phase III trial of SLS-002 for ASIB in patients with MDD.

As a result of the scheduling 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 take advantage of the FDA's expedited programs for drug development and review.

SLS-005is IV Trehalose, a protein stabilizer that crosses the blood-brain-barrier, activates autophagy and lysosomal biogenesis. Based on the pre-clinical and in-vitro studies, there is a sound scientific rationale for developing Trehalose for the treatment of Sanfilippo syndrome. Trehalose is a low molecular weight disaccharide (.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 mg/mL IV solution has demonstrated promising clinical potential in prior Phase II clinical development for OPMD and SCA3, also known as Machado Joseph disease, with a good safety profile 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 two U.S. patents for parenteral administration of Trehalose for patients with OPMD and SCA3, both of which are expected to expire in 2033. In addition, Orphan Drug Designation for OPMD and SCA3 has been secured in the U.S. and in the EU. In February 2019, we assumed a collaborative agreement with TSF, a nonprofit medical research foundation founded by parents of children with Sanfilippo syndrome. SLS-005 will be studied in a clinical trial which is a combined Phase IIb/III, multicenter study designed to assess safety, tolerability and efficacy of IV Trehalose in Sanfilippo syndrome A and B patients. Outcome measures include functional outcomes, biomarkers, neuro-cognitive assessments and quality of life measurements. Additionally, we intend to conduct a second study that will include Sanfilippo syndrome C and D patients as well as Sanfilippo syndrome A and B patients who do not meet the criteria of inclusion for the Phase IIb/III study into a separate expanded patient access study. On July 15, 2019, we amended the agreement whereby we agreed to assume responsibility for the 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.

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 PD, SLS-008, targeted at chronic inflammation in asthma and orphan indications such as pediatric esophagitis, SLS-010 in narcolepsy and related disorders and SLS-012, an injectable therapy for post-operative pain management.

SLS-004 is an all-in-one lentiviral vector, targeted for gene editing through DNA methylation within intron 1 of the SNCA gene responsible for expressing alpha- synuclein protein. SLS-004, when delivered to dopaminergic neurons derived from human induced pluripotent stem cells (hiPSCs) of a PD patient, modified the expression on alpha-synuclein and exhibited reversal of the disease-related cellular-phenotypes characteristics of the neurons.

The multiplication and/or mutation of the SNCA gene has been implicated as a highly significant risk factor for PD, as it leads to overexpression of alpha-synuclein protein that misfolds into alpha-synuclein aggregates that comprise the Lewy bodies and Lewy neurites. In addition, accumulative evidence suggests that elevated levels of alpha-synuclein are causative in the pathogenesis of PD. The role of mutated SNCA in PD pathogenesis and the need to maintain the normal physiological levels of alpha-synuclein protein emphasize the so-far unmet need to develop new therapeutic strategies, such as SLS-004, targeting the regulatory mechanism of alpha-synuclein expression.

SLS-006 is a true partial dopamine agonist, originally developed by Wyeth Pharmaceuticals, Inc., with previous clinical studies on 340 subjects in various Phase I and Phase II studies. It is a potent D2/D3 agonist/antagonist that has shown promising efficacy with statistical significance in Phase II studies in early stage PD patients and an attractive safety profile. Moreover, it has also shown synergistic effect with reduced doses of L-DOPA. We are evaluating studies to advance the product candidate into late stage trials.

SLS-007 is a rationally designed peptide-based approach, targeting the NACore (nonamyloid component core) of alpha-synuclein to inhibit the protein from aggregation. Recent in-vitro and cell culture research have shown 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-alpha-synuclein peptidic inhibitors.

SLS-008 is an orally available antagonist for Chemoattractant Receptor-homologous molecules expressed on TH2 cells ("CRTh2"), targeted at chronic inflammation in asthma and a pediatric orphan indication. We have a "family" of compounds under our SLS-008 program. We intend to file an IND after completion of IND-enabling studies, which are currently in progress, in an undisclosed pediatric orphan indication where there is a high unmet need for an effective oral therapy.

Additionally, we are developing several preclinical programs, most of which have well-defined mechanisms of action, including:

- SLS-010, an oral histamine H3A receptor antagonist that shows promising activity in narcolepsy and related disorders; and
- SLS-012, an injectable therapy for post-operative pain management.

Acquisition of Assets from Bioblast

On February 15, 2019, we entered into 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. At the Bioblast Closing, we paid to Bioblast $1.5 million in cash, and we agreed to pay to Bioblast an additional $2.0 million in cash by the one-year anniversary of the Bioblast Closing. 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 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, a nonprofit medical research foundation founded by parents of children with Sanfilippo syndrome. TSF, upon approval by the FDA, plans to begin a Phase II(b)/III clinical trial in up to 24 patients with Sanfilippo syndrome, which is now known under the study name SLS-005. We will provide the clinical supply of Trehalose. The terms of the Bioblast Asset Purchase Agreement entitle us to access all clinical data from this trial. On July 15, 2019, we amended the agreement whereby we agreed to assume responsibility for the 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 The Regents of the University of California

On March 7, 2019, we entered into the UC Regents License Agreement 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 alpha-synuclein (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 the completion of 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 the Duke License Agreement pursuant to which we were granted an exclusive license to a gene therapy program targeting the regulation of the SNCA gene, which encodes alpha-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. Under the terms of the Duke License Agreement, 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.

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 suicidality in MDD and PTSD;
- Advancing SLS-005 in Sanfilippo syndrome;
- Advancing SLS-004 in PD;
- Advancing SLS-006 in PD;
- Advancing SLS-007 in PD as a monotherapy;
- Filing an IND for SLS-008 in pediatric esophagitis and another undisclosed indication;
- Forming strategic collaborations in the EU and Asian markets; and
- Acquiring synergistic assets in the central nervous system therapy space through licensing and partnerships.

We also have two legacy product candidates: a product candidate in the United States for the treatment of ED, which we in-licensed from Warner Chilcott Company, Inc., now a subsidiary of Allergan; 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

Revenues

We recorded $375,000 and $0 in grant revenue during the year ended December 31, 2019 and 2018, respectively. The $375,000 increase in revenue in 2019 was related to our amended agreement with TSF, pursuant to which we agreed to assume responsibility for the 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.

Operating Expense

Operating expense was as follows (in thousands):

	Year Ended December 31,	
	2019	**2018**
Operating expense		
Research and development	$ 22,563	$ 553
General and administrative	7,559	2,631
Total operating expense	$ 30,122	$ 3,184

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 $22.0 million increase in R&D expense during the year ended December 31, 2019, as compared to the same period in 2018, are as follows (in thousands):

	Year Ended December 31,	
	2019	**2018**
Research and development expenses		
Cash payments for licenses	$ 8,733	$ 400
Non-cash payments licenses	5,250	-
Clinical trial expenses	2,821	-
Manufacturing expenses	2,706	27
Employee compensation	1,718	-
Contract consulting expenses	1,132	126
Other research and development expenses	203	-
Total research and development expenses	$ 22,563	$ 553

The $22.0 million increase in R&D expense during the year ended December 31, 2019, as compared to the same period in 2018, resulted primarily from the $8.7 million for cash payments made or accrued for licenses for SLS-002, SLS-004, SLS-005 and SLS-007, $5.3 million in non-cash charges for common stock issued for licenses for SLS-002 and SLS-006. The increase was also due to clinical trial costs of approximately $2.8 million, manufacturing costs approximately $2.7 million, $1.7 million in employee related costs for personnel that were hired during the year and $1.1 million for contract consulting expenses.

General and Administrative Expenses

General and administrative ("G&A") costs include expenses for personnel, finance, legal, business development and investor relations. General and administrative expenses increased by $4.9 million during the year ended December 31, 2019, as compared to the same period in 2018. This increase was primarily due to $2.0 million for costs associated with the Merger for legal and administrative costs which we do not expect to continue going forward. This increase was also due to costs associated with becoming a publicly traded company on January 24, 2019, including by not limited to, legal, insurance, investor relations, accounting and Nasdaq listing fee costs of approximately $1.7 million and approximately $600,000 in employee-related costs for personnel that were hired during the year.

Other Income and Expense

Other income and expense was as follows (in thousands):

	Year Ended December 31,	
	2019	**2018**
Other income (expense)		
Interest income	$ 151	$ -
Interest expense	(29)	(131)
Loss on warrant issuance	(5,020)	-
Change in fair value of warrant liabilities	(16,501)	-
Change in fair value of convertible notes payable	(109)	(160)
Total other expense	$ (21,508)	$ (291)

Interest Income

Interest income was $151,000 and $0 for the year ended December 31, 2019 and 2018, respectively. The increase is due to investing excess cash during the year ended December 31, 2019.

Interest Expense

Interest expense was $29,000 and $131,000 for the year ended December 31, 2019 and 2018, respectively. The decrease is due to the conversion of all the outstanding convertible notes on January 24, 2019, offset partially by interest expense for the financing of our director and officer liability insurance policies during 2019.

Loss on warrant issuance

Loss on warrant issuance was $5.0 million and $0 for the year ended December 31, 2019 and 2018, respectively. The loss was due to the fair value of the warrants exceeding the net cash proceeds from the Merger.

Change in Fair Value of Warrant Liability

The fair value of warrant liability was $963,000 at December 31, 2019. The change in fair value of warrant liabilities of $16.5 million is due to revaluation of the two series of warrants to purchase shares of common stock issued on January 24, 2019 (the "Series A Warrants" and the "Series B Warrants" and, together, the "Pre-Merger Warrants") pursuant to that certain Securities Purchase Agreement by and among Apricus, STI and the investors listed on the Schedule of Buyers attached thereto (the "Pre-Merger SPA") during the year ended December 31, 2019.

Change in Fair Value of Convertible Notes Payable

The convertible notes were converted into common stock pursuant to the Merger on January 24, 2019. The change in fair value of convertible notes was an expense of $109,000 and $160,000 during the year ended December 31, 2019 and 2018, respectively.

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, 2019, we had $10.3 million in cash and an accumulated deficit of $56.1 million. We have historically funded our operations through the issuance of convertible notes (the "Notes") (see Note 6 to our consolidated financial statements), the sale of common stock (see Note 3 to our consolidated financial statements) and the exercise of warrants (see Note 7 to our consolidated financial statements).

On February 13, 2020, we completed an underwritten public offering pursuant to which we sold 6,666,667 shares of our common stock at a price to the public of $0.75 per share. On February 19, 2020, we sold an additional 999,999 shares of our common stock at a price to the public of $0.75 per share pursuant to the full exercise of the underwriters' option to cover over-allotments. The net proceeds to us from this offering were approximately $5.0 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us. On March 16, 2020, we completed an additional underwritten public offering pursuant to which we sold 7,500,000 shares of our common stock at a price to the public of $0.60 per share. The net proceeds to us from this offering were approximately $3.9 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us.

On August 23, 2019, we entered into a Securities Purchase Agreement with certain institutional investors (the "Securities Purchase Agreement"), pursuant to which we agreed to issue and sell an aggregate of 4,475,000 shares of common stock in a registered direct offering, resulting in total gross proceeds of approximately $6.7 million, before deducting the placement agents' fees and other estimated offering expenses (see Note 3 to our consolidated financial statements). We also agreed to issue to the investors unregistered 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 have an exercise price of $1.78 per share of common stock, will be exercisable six months from the date of issuance and will expire four years following the date of issuance. The

combined purchase price for one share and one warrant to purchase half of a share of common stock in the offerings was $1.50.

On June 17, 2019, we entered into an Equity Distribution Agreement (the "Equity Distribution Agreement") with Piper Jaffray & Co., as sales agent ("Piper Jaffray"), pursuant to we may offer and sell, from time to time, through Piper Jaffray up to $50,000,000 in shares of our common stock. During the year ended December 31, 2019, we sold 1,197,676 shares for net proceeds of approximately $2.6 million pursuant to the Equity Distribution Agreement (see Note 3 to our consolidated financial statements). On August 23, 2019, we suspended our continuous offering under the Equity Distribution Agreement.

Through October 31, 2018, we obtained proceeds of $2.3 million from the issuance of convertible notes (the "Notes"). These Notes accrued 8% interest and would have matured on April 30, 2019. The Notes were convertible into shares of common stock upon a preferred stock equity raise of greater than $1,000,000 at 80% or 90% of the lowest purchase price per share paid by another investor in a qualified financing. The Notes were converted into 172,284 shares of common stock on January 24, 2019 pursuant to the closing of the Merger.

On October 16, 2018, we entered into the Pre-Merger SPA. Pursuant to the Pre-Merger SPA, among other things, we issued to the Buyers (i) an aggregate of 1,829,406 shares of common stock and (ii) the Pre-Merger Warrants for an aggregate purchase price of approximately $18.0 million, in connection with the closing of the Merger (net proceeds of $16.5 million, after payment of transaction expenses). We issued the Pre-Merger Warrants on January 31, 2019 and on February 14, 2019, we registered the resale of common stock underlying the Pre- Merger Warrants as required by the registration rights agreement that we entered into on October 16, 2018 in connection with the Pre-Merger SPA. 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 to 2,640,128 shares of common stock at an exercise price per share equal to $2.3005 on February 27, 2019 and which was further adjusted to 3,629,023 shares of common stock at an exercise price per share equal to $1.6736 on March 7, 2019, in each case, pursuant to the terms thereof. Effective August 23, 2019, pursuant to the terms of the Series A Warrants, the exercise price of the Series A Warrants automatically decreased from $1.6736 per share to $0.9267 per share as a result of the announcement of the issuance of the August 2019 Warrants pursuant to the Securities Purchase Agreement. The Series A Warrants were immediately exercisable upon issuance and have a term of five years from the date of issuance. The Series B Warrants were initially exercisable for no shares of common stock, which was adjusted to 7,951,090 shares of common stock on February 27, 2019 and which was further adjusted to 11,614,483 shares of common stock on March 7, 2019, in each case, pursuant to the terms thereof. The Series B Warrants had an exercise price of $0.001, were immediately exercisable upon issuance and had an expiration date of the day following the later to occur of (i) the Reservation Date (as defined therein) and (ii) the date on which the Series B Warrants have been exercised in full (without giving effect to any limitation on exercise contained therein) and no shares remain issuable thereunder.

During the year ended December 31, 2019, we received approximately $4.5 million in proceeds from the exercise of approximately 14.3 million Series A Warrants and Series B Warrants.

We expect to use the net proceeds from the above transaction 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. In addition, pursuant to the asset purchase agreement, as amended, with Vyera, we will be required to make cash payments to Vyera in the amounts of $1.0 million and $1.0 million in April 2020 and July 2020, respectively. Pursuant to the amended and restated license agreement with Stuart Weg, M.D., we will be required to make a cash payment to Dr. Weg in the amount of $0.125 million in January 2021 and, if certain conditions are not met, make an additional cash payment of $0.2 million in January 2022. We believe that in order for us to meet our obligations arising from normal business operations for the next twelve months, we require additional capital in the form of equity, debt or both. Without additional capital, our ability to continue to operate will be limited. These financial statements do not include any adjustments to the recoverability and classification of recorded assets amounts and classification of liabilities that might be necessary should we not be able to continue as a going concern.

We currently have an effective shelf registration statement on Form S-3 filed with the SEC. As further discussed in the risk factor "As a result of our failure to timely file our Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, we are currently ineligible to file new short form registration statements on Form S-3, which may impair our ability to raise capital on terms favorable to us, in a timely manner or at all.", we will no longer be permitted to use our existing registration statements on Form S-3, including our shelf registration statement on Form S-3, as of the filing date of this Annual Report on Form 10-K for the fiscal year ended December 31, 2019. Absent a waiver of the Form S-3 eligibility requirements and assuming we continue to timely file our required reports under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the earliest we would regain the ability to use Form S-3 is June 1, 2020. At that time, provided that we are otherwise current in our Exchange Act reporting obligations, we would become eligible to 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. As of February 27, 2020, we had approximately $84.8 million available under our Form S-3 shelf registration statement. However if, and/or when, we regain eligibility to use our shelf registration statement on Form S-3, under current SEC regulations, in the event the aggregate market value of our common stock held by non-affiliates ("public float") is less than $75.0 million, the amount we can raise through primary public offerings of securities, including sales under the Equity Distribution Agreement, in any twelve-month period using shelf registration statements is limited to an aggregate of one-third of our public float. SEC regulations permit us to use the highest closing sales price of our common stock (or the average of the last bid and last ask prices of our common stock) on any day within 60 days of sales under the shelf registration statement. As of February 27, 2020, our public float was approximately $51.9 million based on 36.5 million shares of our common stock outstanding at a price of $1.56 per share, which was the closing sale price of our common stock on January 8, 2020. As our public float was less than $75.0 million as of February 27, 2020, our usage of our S-3 shelf registration statement is limited. We still maintain the ability to raise funds through other means, such as through the filing of a registration statement on Form S-1 or in private placements. The rules and regulations of the SEC or any other regulatory agencies may restrict our ability to conduct certain types of financing activities, or may affect the timing of and amounts we can raise by undertaking such activities.

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;
- the extent and amount of any indemnification claims, including any made by Ferring International Center S.A. ("Ferring") under the asset purchase agreement with Ferring, entered into on March 8, 2017, pursuant to which we sold to Ferring our ex-U.S. assets and rights related to products in development, intended for the topical treatment of ED, which are known as Vitaros in certain countries outside of the United States;
- 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;
- our ability to secure a development partner for our product candidate in the United States for the treatment of ED (the "CVR Product Candidate") in order to overcome deficiencies raised in the 2018 complete response letter issued by the FDA related to the CVR Product Candidate; and
- our ability to increase the number of authorized shares outstanding to facilitate future financing events.

We will need to raise substantial additional funds 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.

On November 6, 2019, we received written notice (the "Notice") from The Nasdaq Stock Market LLC ("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 4, 2020, to regain compliance. The Notice stated that the Nasdaq Staff would provide written notification that we have achieved compliance with Rule 5550(a)(2) if at any time before May 4, 2020, the bid price of our common stock closes at $1.00 per share or more for a minimum of ten consecutive business days. The Notice had no immediate effect on the listing or trading of our common stock and the common stock continued to trade on the Nasdaq Capital Market under the symbol "SEEL."

If we did not regain compliance with Rule 5550(a)(2) by May 4, 2020, we may have been eligible for an additional 180 calendar day compliance period. To qualify, we would have been 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, with the exception of the bid price requirement, and would have needed to provide written notice of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. However, if it appeared to the Nasdaq Staff that we would not be able to cure the deficiency, or if we were otherwise not eligible, Nasdaq would have notified us that our securities would be subject to delisting. In the event of such a notification, we may have appealed the Nasdaq Staff's determination to delist our securities, but there could have been no assurance the Nasdaq Staff would grant any request for continued listing.

On December 26, 2019, we were notified by the Nasdaq Staff that for more than the last 10 consecutive business days, from December 6, 2019 through December 24, 2019, the closing bid price of our common stock had been at $1.00 per share or greater. Accordingly, we have regained compliance with Listing Rule 5550(a)(2) and this matter is now closed. While we have regained compliance with the Nasdaq Capital Market's continued listing requirements, there is no guarantee that we will remain in compliance with such listing requirements in the future. Failure to comply with the Nasdaq Capital Market's continued listing requirements could result in delisting of our common stock from the Nasdaq Capital Market, which could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all.

Cash Flow Summary

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

	Year Ended December 31,	
	2019	**2018**
Net cash provided by (used in) operations		
Net cash used in operating activities	$ (19,305)	$ (1,581)
Net cash provided by financing activities	$ 29,524	$ 1,365
Net increase (decrease) in cash	$ 10,219	$ (216)

Operating Activities

Cash used in operating activities of $19.3 million in the year ended December 31, 2019 was primarily due to the net loss of $51.3 million, which was partially offset by changes in the fair value of the warrant liabilities of $16.5 million, changes in operating assets and liabilities of $6.9 million, $3.0 million in non-cash expense for the acquisition of licenses for research and development, and the loss on warrant issuance of $5.0 million.

Cash used in operating activities of $1.6 million during the year ended December 31, 2018 was primarily due to a net loss of $3.5 million, net of adjustments to net loss for changes in accounts payable and accrued expenses of $1.7 million.

Investing Activities

No cash was used in investing activities during the years ended December 31, 2019 or 2018.

Financing Activities

Cash provided by financing activities of $29.5 million in the year ended December 31, 2019 was primarily due to the proceeds from the exercise of warrants, the proceeds from the issuance and sale of common stock pursuant to the Securities Purchase Agreement, the proceeds from the issuance and sale of common stock and warrants pursuant to the Pre-Merger SPA and proceeds from the issuance and sale of common stock pursuant to the Equity Distribution Agreement.

Cash provided by financing activities of $1.4 million during the year ended December 31, 2018 was due to proceeds from the issuance of convertible notes during the year ended December 31, 2018.

Contractual Obligations

We have entered into long-term agreements with certain manufacturers and suppliers that require us to make contractual payment to these organizations. 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.

The following represents our contractual obligations as of December 31, 2019 (in thousands):

Contractual Obligations	Total	Less than 1 year	2-3 years	4-5 years	More than 5 years
Operating leases	$ 32	$ 32	$ -	$ -	$ -
Cash payments for license fees	5,175	4,850	325	-	-
Non-cash payments for license fees	2,250	2,250	-	-	-
Purchase obligations (1)	6,645	6,645	-	-	-
Office lease	33	33	-	-	-

(1) Purchase obligations primarily represent commitments for agreements with external service providers, under which we will incur expenses relating to clinical trials of SLS-002 and SLS-005 and other clinical candidates. These agreements are cancellable on notice of up to three months.

Off-Balance Sheet Arrangements

As of December 31, 2019, we did not have any off-balance sheet arrangements as defined in Item 303(a)(4)(ii) of Regulation S-K.

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 8 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.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

P>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, 2019 and 2018, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2019, 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 1 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 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the 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 audits 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 audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2017

Short Hills, New Jersey
March 17, 2020

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

	December 31,	
	2019	**2018**
Assets		
Current assets		
Cash	$ 10,261	$ 42
Deferred offering costs	-	140
Prepaid expenses and other current assets	835	9
Total current assets	11,096	191
Total assets	$ 11,096	$ 191
Liabilities and stockholders' equity (deficit)		
Current liabilities		
Accounts payable	$ 796	$ 2,220
Accrued expenses	1,919	84
Licenses payable	7,100	-
Accrued interest	-	151
Convertible notes payable, at fair value	-	2,442
Warrant liabilities, at fair value	963	-
Total current liabilities	10,778	4,897
Licenses payables, long-term	325	-
Total liabilities	11,103	4,897
Commitments and contingencies (note 11)		
Stockholders' deficit		
Preferred stock, $0.001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of December 31, 2019 and 2018	-	-
Common stock, $0.001 par value, 120,000,000 shares authorized, 27,028,533 and 3,081,546 issued and outstanding as of December 31, 2019 and 2018, respectively	27	3
Additional paid-in-capital	56,027	97
Accumulated deficit	(56,061)	(4,806)
Total stockholders' deficit	(7)	(4,706)
Total liabilities and stockholders' deficit	$ 11,096	$ 191

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 per share data)

	Year Ended December 31,	
	2019	**2018**
Revenues		
Grant revenue	$ 375	$ -
Total revenues	375	-
Operating expense		
Research and development	22,563	553
General and administrative	7,559	2,631
Total operating expense	30,122	3,184
Loss from operations	(29,747)	(3,184)
Other income (expense)		
Interest income	151	-
Interest expense	(29)	(131)
Loss on warrant issuance	(5,020)	-
Change in fair value of warrant liabilities	(16,501)	-
Change in fair value of convertible notes payable	(109)	(160)
Total other expense	(21,508)	(291)
Net loss and comprehensive loss	$ (51,255)	$ (3,475)
Net loss per share basic and diluted	$ (2.52)	$ (1.13)
Weighted-average common shares outstanding basic and diluted	20,308,818	3,081,546

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)

	Common Stock (Shares)	Common Stock (Amount)	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
Balance as of December 31, 2017	3,081,546	$ 3	$ 64	$ (1,331)	$ (1,264)
Stock-based compensation expense	-	-	33	-	33
Net loss	-	-	-	(3,475)	(3,475)
Balance as of December 31, 2018	3,081,546	3	97	(4,806)	(4,706)
Stock-based compensation expense	-	-	459	-	459
Issuance of common stock and warrants in a private offering, net of $16.5 million warrant liability	1,829,407	2	-	-	2
Effect of reverse merger	947,218	1	(300)	-	(299)
Warrants exercised for cash	14,332,620	14	4,503	-	4,517
Issuance of common stock for license acquired	992,782	1	2,999	-	3,000
Reclass of warrant liabilities related to Series A warrants exercised for cash	-	-	5,600	-	5,600
Reclass of Series B warrants from warrant liability to stockholders' equity	-	-	31,473	-	31,473
Issuance of common stock for conversion of debt and accrued interest	172,284	-	2,715	-	2,715
Issuance of common stock and warrants, pursuant to Securities Purchase Agreement, net of issuance costs	4,475,000	5	5,915	-	5,920
Issuance of common stock in at-the-market offering, net of issuance costs	1,197,676	1	2,566	-	2,567
Net loss	-	-	-	(51,255)	(51,255)
Balance as of December 31, 2019	27,028,533	$ 27	$ 56,027	$ (56,061)	$ (7)

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,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (51,255)	$ (3,475)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	459	33
Research and development expensed - license acquired	3,000	-
Change in fair value of convertible notes payable	109	160
Change in fair value of warrant liability	16,501	-
Loss on warrant issuance	5,020	-
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	(686)	(6)
Accounts payable	(1,424)	1,672
Accrued expenses	1,533	(96)
Accrued interest	13	131
Current portion of licenses payable	7,100	-
Licenses payable, long-term	325	-
Net cash used in operating activities	(19,305)	(1,581)
Cash flows provided by financing activities		
Proceeds from issuance of common stock and warrants in a private offering	16,520	-
Proceeds from issuance of common stock and warrants, pursuant to Securities Purchase Agreement, net of issuance costs	5,920	-
Proceeds from issuance of common stock in at-the-market offering	2,567	-
Proceeds from exercise of warrants	4,517	-
Proceeds from convertible notes	-	1,365
Net cash provided by financing activities	29,524	1,365
Net increase (decrease) in cash	10,219	(216)
Cash, beginning of period	42	258
Cash, end of period	$ 10,261	$ 42
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 16	$ -
Cash paid for income taxes	$ -	$ -
Non-cash investing and financing activities:		
Issuance of common stock for conversion of debt	$ 2,551	$ -
Issuance of common stock for conversion of accrued interest	$ 164	$ -
Issuance of common stock for license acquired	$ 3,000	$ -
Effect of reverse merger	$ 299	$ -
Reclass of warrant liabilities related to Series A warrants exercised for cash	$ 5,600	$ -
Reclass of Series B warrants from warrant liability to stockholders' equity	$ 31,473	$ -
Deferred offering costs	$ -	$ 140

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

Notes to Consolidated Financial Statements

1. Organization and Summary of Significant Accounting Policies

Organization

Seelos Therapeutics, Inc. and Subsidiaries ("Seelos" or the "Company") is a Nevada corporation that was initially formed in 1987. The Company is a clinical-stage biopharmaceutical company focused on developing novel technologies and therapeutics for the treatment of central nervous system, respiratory and other disorders.

Merger with Apricus Biosciences, Inc.

On January 24, 2019, Apricus Biosciences, Inc., a Nevada corporation ("Apricus"), 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 subsidiary of Apricus merged with and into STI, with STI (renamed as "Seelos Corporation") continuing as a wholly owned subsidiary of Apricus and the surviving corporation of the merger and (ii) Apricus was renamed as "Seelos Therapeutics, Inc." (the "Merger").

The Merger was accounted for as a reverse recapitalization under United States generally accepted accounting principles ("U.S. GAAP") because the primary assets of Apricus were nominal following 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's stockholders and other persons holding securities convertible, exercisable or exchangeable directly or indirectly for STI common stock owned the majority of Apricus 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. Accordingly, the historical financial statements of STI became the Company's historical financial statements, including the comparative prior periods.

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, valuation of common stock 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.

Liquidity

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, 2019, the Company had $10.3 million in cash and an accumulated deficit of $56.1 million. The Company has historically funded its operations through the issuance of convertible notes (see Note 6), the sale of common stock (see Note 3) and the exercise of warrants (see Note 7).

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 release date of this Annual Report on Form 10-K. Based on such evaluation and the Company's current plans, which are subject to change, management believes that the Company's existing cash and cash equivalents as of December 31, 2019 are not sufficient to satisfy its operating cash needs for at least one year.

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 believes it will need to raise substantial additional funds 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.

Fair Value of Financial Instruments

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

Leases

Effective January 1, 2019, the Company records a right-of use ("ROU") asset and a lease liability on its balance sheet for all leases with terms of 12 months or longer. Leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. Historically, the Company recorded rent expense associated with its operating lease on a straight-line basis over the term of the lease. The difference between rent payments and straight-line rent expense was recorded as deferred rent in accrued liabilities.

As of December 31, 2019, the Company's leases had original terms of 12 months or less. The Company does not recognize ROU assets and lease liabilities that arise from leases with an original term of 12 months or less. Rather the Company recognizes the lease payments on a straight-line basis over the term of the lease.

Fair Value Measurements

The Company follows the accounting guidance in the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("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 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 transfers between fair value measurement levels during the years ended December 31, 2019 and 2018 (in thousands):

	Fair Value Measurements as of December 31, 2019			
	(Level 1)	(Level 2)	(Level 3)	Total
Assets				
Cash	$ 10,261	$ -	$ -	$ 10,261
Liabilities				
Warrant liabilities, at fair value	$ -	$ -	$ 963	$ 963

	Fair Value Measurements as of December 31, 2018			
	(Level 1)	(Level 2)	(Level 3)	Total
Assets				
Cash	$ 42	$ -	$ -	$ 42
Liabilities				
Convertible notes payable, at fair value	$ -	$ -	$ 2,442	$ 2,442

The common stock warrant liabilities were recorded at fair value using the Black-Scholes option pricing model. There were no liability classified warrants as of December 31, 2018. 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, 2019:

	Year Ended December 31, 2019
Risk-free interest rate	1.66%
Volatility	110.80%
Dividend yield	- %
Expected term	4.07
Weighted average fair value	$ 1.06

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

	Warrant liabilities
Balance as of December 31, 2018	$ -
Warrant issued in connection with financing	21,535
Warrant liability reclassified to stockholders' equity	(37,073)
Change in fair value measurement of warrant liability	16,501
Balance as of December 31, 2019	$ 963

Of the inputs used to value the outstanding common stock warrant liabilities as of December 31, 2019, the most subjective input is the Company's estimate of expected volatility of its common stock.

Fair Value Option

As permitted under ASC Topic 825, Financial Instruments ("ASC 825"), the Company had elected the fair value option to account for its convertible notes. In accordance with ASC 825, the Company records these convertible notes at fair value with changes in fair value recorded in the Statement of Operations. 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.

Grant Revenue

The Company determined that its grant agreement with Team Sanfilippo Foundation ("TSF"), a nonprofit medical research foundation founded by parents of children with Sanfilippo syndrome, is within the scope of ASC Topic 606 "Revenue from Contracts with Customers". Under the TSF agreement, TSF makes certain milestone payments to the Company as certain milestones related to a specified Phase II/III clinical trial, defined in the agreement, are met. The Company determined that there is one performance obligation under the TSF agreement. The variable consideration, in the form of milestone payments, is attributed to the completed portion of the performance obligation that triggers or results in the payments. During the year ended December 31, 2019, the Company recognized $375,000 of revenue from a milestone payment received as the milestone payment represents the Company's completed portion of its performance obligation.

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, 2019 and 2018 have been excluded from the computation of diluted weighted average shares outstanding, as they would be anti-dilutive (in thousands):

	Year Ended December 31,	
	2019	**2018**
Outstanding stock options	522	31
Outstanding warrants	3,584	-
Convertible notes	-	273
	4,106	304

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.

Segment Information

The Company operates under one segment which develops pharmaceutical products.

Recent Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-02, Leases ("ASU 2016-02"). The new standard establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company adopted ASU 2016-02 on January 1, 2019 and the adoption of the standard did not have a material effect on its consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820), Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement ("ASU 2018-13"). The amendments in this ASU require certain existing disclosure requirements in Topic 820 to be modified or removed, and certain new disclosure requirements to be added to the Topic. In addition, this ASU allows entities to exercise more discretion when considering fair value measurement disclosures. ASU 2018-13 will be effective for the Company beginning January 1, 2020 with early adoption permitted. The Company is in the process of evaluating the impact of ASU 2018-13 on its consolidated financial statements and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"), which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The Company is currently evaluating the impact of this standard on its consolidated financial statements and related disclosures.

2. Business Combination

On January 24, 2019, Apricus completed the business combination with STI in accordance with the terms of the Merger Agreement.

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, 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. STI is entitled to retain the first $500,000 and 10% of any Contingent Payments. STI assigned no value to the CVR Product Candidate intangible asset as of December 31, 2019 or the CVR in the acquisition accounting.

3. Common Stock Offerings

Securities Purchase Agreement

On August 23, 2019, the Company entered into a Securities Purchase Agreement with certain institutional investors (the "Securities Purchase Agreement"), pursuant to which the Company issued and sold an aggregate of 4,475,000 shares of common stock in a registered direct offering, resulting in total gross proceeds of approximately $6.7 million, before deducting the placement agents' fees and other estimated offering expenses. The shares were offered by the Company pursuant to the Company's shelf registration statement on Form S-3 filed with the Securities and Exchange Commission ("SEC") on November 2, 2017, as amended. The Company issued to the investors unregistered 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 have an exercise price of $1.78 per share of common stock, will be exercisable six months from the date of issuance and will expire four years following the date of issuance. The combined purchase price for one share and one warrant to purchase half of a share of common stock in the offerings was $1.50. The closing of the offerings occurred on August 27, 2019. The Company filed a registration statement on Form S-1 on November 21, 2019 to provide for the resale of the shares of common stock issuable upon the exercise of the August 2019 Warrants (the "Warrant Shares"), and is obligated to use commercially reasonable efforts to keep such registration statement effective from the date the warrants initially become exercisable until the earlier of (i) the date on which the Warrant Shares may be sold without registration pursuant to Rule 144 under the Securities Act during any 90 day period, and (ii) the date on which no purchaser owns any warrants or Warrant Shares. On August 23, 2019, the Company also entered into a Placement Agency Agreement (the "Placement Agency Agreement") with Roth Capital Partners, LLC ("Roth"), pursuant to which Roth agreed to serve as the placement agent for the issuance and sale of the shares and the warrants, and the Company paid Roth an aggregate fee equal to 7.0% of the gross proceeds received by the Company in the offerings. The Placement Agency Agreement includes indemnity and other customary provisions for transactions of this nature.

Equity Distribution Agreement

On June 17, 2019, the Company entered into an Equity Distribution Agreement (the "Equity Distribution Agreement")with Piper Jaffray & Co., as sales agent ("Piper Jaffray"), pursuant to which the Company may offer and sell, from time to time, through Piper Jaffray (the "Offering") up to $50,000,000 in shares. Any shares offered and sold in the offering will be issued pursuant to the Company's shelf registration statement on Form S-3 filed with the SEC on November 2, 2017, as amended on December 1, 2017 and declared effective on December 7, 2017, the prospectus supplement relating to the offering filed with the SEC on June 17, 2019 and any applicable additional prospectus supplements related to the offering that form a part of the registration statement. The number of shares eligible for sale under the Equity Distribution Agreement will be subject to the limitations of General Instruction I.B.6 of Form S-3. Subject to the terms and conditions of the Equity Distribution Agreement, Piper Jaffray will use its commercially reasonable efforts to sell the shares from time to time, based upon the Company's instructions. Under the Equity Distribution Agreement, Piper Jaffray may sell the shares by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the "Securities Act"), including sales made directly on the Nasdaq Capital Market or on any other existing trading market for the shares. Subject to the Company's prior written consent, Piper Jaffray may also sell shares by any other method permitted by law including, but not limited to, privately negotiated transactions. The Company has no obligation to sell any of the shares, and may at any time suspend offers under the Equity Distribution Agreement. The Offering will terminate upon the earlier of (i) the sale of all of the shares, or (ii) the termination of the Equity Distribution Agreement according to its terms by either the Company or Piper Jaffray. The Company and Piper Jaffray may each terminate the Equity Distribution Agreement at any time by giving advance written notice to the other party as required by the Equity Distribution Agreement. Under the terms of the Equity Distribution Agreement, Piper Jaffray will be entitled to a commission at a fixed rate of 3.0% of the gross proceeds from each sale of shares under the Equity Distribution Agreement. The Company will also reimburse Piper Jaffray for certain expenses incurred in connection with the Equity Distribution Agreement, and agreed to provide indemnification and contribution to Piper Jaffray with

respect to certain liabilities, including liabilities under the Securities Act and the Securities Exchange Act of 1934, as amended (the "Exchange Act"). During the year ended December 31, 2019, the Company sold 1,197,676 shares for net proceeds of approximately $2.6 million pursuant to the Equity Distribution Agreement. On August 23, 2019, the Company suspended its continuous offering under the Equity Distribution Agreement.

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 the 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 STIs 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"), 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 7). 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, (i) fixed the aggregate number of shares of common stock issued and issuable pursuant to the Series B Warrants at 11,614,483 (which number includes shares of common stock issued pursuant to exercises of the Series B Warrants on or prior to March 7, 2019), (ii) 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), (iii) reduced the duration of the period during which the Investors were limited in the number of shares of common stock subject to the Series B Warrants that Investors can exercise on a daily basis, such that such period terminated on March 21, 2019, (iv) reduced the duration of the period during which the number of shares of common stock underlying the Series B Warrants would adjust based on the volume-weighted average price of the common stock, such that the adjustment period terminated on March 7, 2019, (v) fixed the "Reset Price" based on which the Series B Warrants adjusted on March 7, 2019 at $1.3389, (vi) amended the Purchase Agreement such that the date until which the Company was restricted from effecting certain variable rate transactions would be March 20, 2019, (vii) amended the Series A Warrants so that any references therein to the Series B Warrants refer to the Series B Warrants, as amended or restated from time to time, and (viii) made certain other technical, conforming and clarifying changes. 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.

Effective August 23, 2019, pursuant to the terms of the Series A Warrants, the exercise price of the Series A Warrants automatically decreased from $1.6736 per share to $0.9267 per share as a result of the announcement of the issuance of the August 2019 Warrants pursuant to the Securities Purchase Agreement.

At December 31, 2019, 0.9 million Series A Warrants remain unexercised. All Series B Warrants were exercised during the year ended December 31, 2019.

4. 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.

As consideration for the grant of the rights and licenses under the License Agreement, the Company paid to Ligand a nominal option fee. The Company was obligated to pay to Ligand an aggregate of $1.3 million within 30 days after the closing of the issuance and sale by the Company of debt and/or equity securities for gross proceeds to the Company of at least $7.5 million. In connection with the closing of the Merger, the Company issued 392,307 shares of common stock to settle this obligation. As further partial consideration for the grant of the rights and licenses to the Company by Ligand under the License Agreement, the Company 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 the Company in the event of the Company's initial public offering or a financing transaction consummated in connection with a transaction as a result of which the Company becomes owned or controlled by an existing issuer with a class of securities registered under the Exchange Act and immediately after such transaction, the security holders of the Company 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 the Company in the event the Company is acquired. In connection with the closing of the Merger, the Company issued 408,946 shares of common stock to settle this milestone payment obligation.

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, 2019.

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

On May 25, 2017, the Company entered into a non-binding term sheet to acquire TUR-002 (intranasal ketamine), which is now known as SLS-002, from Vyera. During the year ended December 31, 2017, the Company recorded $400,000 in research and development expenses related to the non-refundable but creditable payments to continue to negotiate exclusively with Vyera while the Company continued to identify financing terms with other parties to provide the necessary funding to purchase SLS-002.

On January 18, 2018, the Company and Vyera entered into an Amendment to the May 25, 2017 term sheet for SLS-002. The Company paid $100,000 as a non-refundable but creditable payment to continue to negotiate exclusively with Vyera to purchase SLS-002.

On March 6, 2018, the Company entered into an Asset Purchase Agreement with Vyera, as amended by an amendment thereto entered into on May 18, 2018 and an amendment thereto entered into on December 31, 2018 (as amended, the "Vyera Agreement"), pursuant to which the Company agreed to acquire the assets (the "Vyera Assets") and liabilities (the "Vyera Assumed Liabilities"), of Vyera related to SLS-002. The Company is obligated to use commercially reasonable efforts to seek regulatory approval in the United States for and commercialize SLS-002. The Company agreed that if it receives regulatory approval to commence a Phase III clinical trial for SLS-002 and no third party has alleged any claim of conflict, infringement, invalidity or other violation of any rights of others with regard to the Vyera Assets, then the Company must commence a Phase III clinical trial for SLS-002 by June 30, 2020 (the "Phase III Obligation"), and if the Company failed to do so, the Vyera Agreement would terminate immediately and become null and void and all of the Vyera Assets and the Vyera Assumed Liabilities would automatically be returned to Vyera. As partial consideration for the Vyera Assets, the Company agreed to make a non-refundable milestone payment of $3.5 million upon dosing of the first patient in a Phase III clinical trial for SLS-002 (the "Dosing Milestone").

In the event that the Company sells, directly or indirectly, all or substantially all of the Vyera Assets to a third party, then the Company must pay Vyera an amount equal to 4% of the net proceeds actually received by the Company as an upfront payment in such sale.

As consideration for the Vyera Assets, the Company paid to Vyera a non-refundable cash payment of $150,000 on May 21, 2018. As further consideration for the Vyera Assets, upon public announcement of the entry by Apricus and STI into the Merger Agreement, the Company paid to Vyera a non-refundable cash payment of $150,000. As further consideration for the Vyera Assets, the Company issued to Vyera 191,529 shares of common stock and paid Vyera a non-refundable cash payment of $1,000,000 on January 29, 2019. The Company agreed to pay to Vyera certain one-time, non-refundable milestone payments consisting of (i) $3.5 million upon dosing of the first patient in a Phase III clinical trial for SLS-002, (ii) $10.0 million upon approval by the FDA of a new drug application (an "NDA"), with respect to SLS-002, (iii) $5.0 million upon approval by the European Medicines Agency (the "EMA") of the foreign equivalent to an NDA with respect to SLS-002 in a Major Market, (iv) $2.5 million upon approval by the EMA of the foreign equivalent to an NDA with respect to SLS-002 in a second Major Market, (v) $5.0 million upon the achievement of $250.0 million in net sales of SLS-002, (vi) $10.0 million upon the achievement of $500.0 million in net sales of SLS-002, (vii) $15.0 million upon the achievement of $1.0 billion in net sales of SLS-002, (viii) $20.0 million upon the achievement of $1.5 billion in net sales of SLS-002, and (ix) $25.0 million upon the achievement of $2.0 billion in net sales of SLS-002. The Company will also pay to Vyera a royalty percentage in the mid-teens on aggregate annual net sales of SLS-002. Also see Note 11.

On October 15, 2019, the Company and Vyera entered into an amendment (the "Amendment") to the Vyera Agreement. Pursuant to the Amendment, the Company remains obligated to use its commercially reasonable efforts to seek regulatory approval in the United States for and commercialize SLS-002. However, the Amendment eliminates the Phase III Obligation discussed above. In addition, in replacement of the Company's obligation to pay the Dosing Milestone, the Company agreed pursuant to the Amendment to (i) issue Vyera in January 2020 that number of registered shares of the Company's common stock equal to $2,250,000 divided by the 30-day volume weighted average price of the common stock calculated prior to such issuance date, provided that the Company may elect, in its sole discretion, to pay Vyera cash (in whole or in part) in lieu of any shares of the Company's common stock and (ii) make cash payments to Vyera in the amounts of $750,000, $750,000, $1.0 million and $1.0 million in October 2019, January 2020, April 2020 and July 2020, respectively (each, a "Payment Obligation"). The Company paid the $750,000 in October 2019 and again in January 2020. On January 2, 2020, the Company entered into a stock purchase agreement with Vyera, pursuant to which the Company issued 1,809,845 shares of the Company's common stock as partial consideration for the Vyera Assets. See Note 12. In event the Company fails to timely meet a Payment Obligation (subject to a cure period), Vyera has the right to require that all of the Vyera Assets and the Vyera Assumed Liabilities be returned to Vyera.

The potential regulatory and commercial milestones are not yet considered probable, and no milestone payments have been accrued at December 31, 2019.

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. 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, 2019.

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 TSF, a nonprofit medical research foundation founded by parents of children with Sanfilippo syndrome. TSF, upon approval by the FDA, planned to begin an open label, Phase II(b) clinical trial in up to 20 patients with Sanfilippo syndrome, which is now known under the study name SLS-005. The Company will provide the clinical supply of Trehalose. The terms of the Bioblast Asset Purchase Agreement entitle the Company access to all clinical data from this trial. On July 15, 2019, TSF and the Company amended the agreement whereby the Company agreed to assume responsibility for the 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, 2019.

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 completion of 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, 2019.

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 alpha-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, 2019.

5. Accrued Expenses

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

	December 31,	
	2019	**2018**
Personnel related	$ 683	$ -
Professional fees	151	84
Outside research and development services	853	-
Other	232	-
Accrued expenses, net	$ 1,919	$ 84

6. Convertible Notes

From May 2017 to October 2018, the Company entered into convertible note agreements with investors for the issuance of convertible notes (the "Notes"). The aggregate principal amount of the Notes was $2.3 million, and the Notes were due no later than April 30, 2019 with simple interest at the rate of 8% per annum. The Notes automatically converted, upon the issuance of preferred stock of the Company for capital-raising purposes occurring on or prior to the Notes' maturity date resulting in gross proceeds in excess of a specific amount, into shares of common stock of the Company by dividing the then-outstanding balance of each convertible note by 80% or 90%, depending on the terms for each note, of the lowest purchase price per share paid, or $9.70 to $10.91 per share, respectively, by another investor in the qualifying financing, which condition was satisfied by the Pre-Merger Financing.

The Notes are carried at fair value. The Company recognized an adjustment relating to changes in the Notes fair value of $109 thousand and $160 thousand during the year ended December 31, 2019 and 2018, respectively.

In connection with the closing of the Merger, the Notes plus unpaid interest were converted into 172,284 shares of common stock at a price of $9.70 or $10.91 per share.

7. Stockholders' Equity

Preferred Stock

The Company is authorized to issue 10.0 million shares of preferred stock, par value $0.001. No shares of preferred stock were outstanding as of December 31, 2019 or 2018.

Common Stock

The Company has authorized 120,000,000 shares of common stock as of December 31, 2019 and had authorized 60,000,000 shares of common stock as of December 31, 2018. 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

August 2019 Warrants

The August 2019 Warrants are exercisable for 2,237,500 shares of common stock at an exercise price per share equal to $1.78. The August 2019 Warrants are exercisable beginning six months after the date of issuance and have a term of four years from the date of issuance.

As of December 31, 2019, 2.2 million August 2019 Warrants 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 to 2,640,128 shares of the common stock at an exercise price per share equal to $2.3005 on February 27, 2019, which was further adjusted to 3,629,023 shares of common stock at an exercise price per share equal to $1.6736 on March 7, 2019, in each case essentially due to trading at a lower price, pursuant to the terms thereof. Effective August 23, 2019, pursuant to the terms of the Series A Warrants, the exercise price of the Series A Warrants automatically decreased from $1.6736 per share to $0.9267 per share as a result of the announcement of the issuance of the August 2019 Warrants pursuant to the Securities Purchase Agreement. The Series A Warrants were immediately exercisable upon issuance and have a term of five years from the date of issuance.

During the year ended December 31, 2019, 2.7 million Series A Warrants were exercised for approximately $4.5 million. As of December 31, 2019, 0.9 million Series A Warrants remain outstanding at an exercise price of $0.9267 per share.

Series B Warrants

The Series B Warrants were initially exercisable for no shares of common stock, which was adjusted to 7,951,090 shares of common stock on February 27, 2019 and which was further adjusted to 11,614,483 shares of common stock on March 7, 2019, in each case essentially due to trading at a lower price, pursuant to the terms thereof. The Series B Warrants had an exercise price of $0.001, were immediately exercisable upon issuance and provided for an expiration date of the day following the later to occur of (i) the Reservation Date (as defined therein), and (ii) the date on which the Series B Warrants have been exercised in full (without giving effect to any limitation on exercise contained therein) and no shares remain issuable thereunder.

During the year ended December 31, 2019, 11.6 million Series B Warrants were exercised for approximately $11,614. As of December 31, 2019, no Series B Warrants remain outstanding and the Series B Warrants are therefore no longer subject to any further changes in warrants or exercise price.

A summary of warrant activity during the year ended December 31, 2019 is as follows (in thousands):

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Outstanding at December 31, 2018	-	$ -	-
Assumed in Merger	437	$ 20.59	3.5
Issued	17,481	$ 0.42	4.1
Exercised	(14,334)	$ 0.31	
Cancelled	-	$ -	
Outstanding as of December 31, 2019	3,584	$ 3.86	3.3
Exercisable as of December 31, 2019	1,346	$ 7.30	2.7

The Series A Warrants and the Series B Warrants were each 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.

8. Stock-Based Compensation

The Company has the Amended and Restated Apricus 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. As of December 31, 2019, an aggregate of 373,798 shares of common stock were authorized under the Apricus 2012 Plan, of which no shares of common stock were available for future grants. Upon completion of the Merger, the Company assumed the Seelos Therapeutics, Inc. 2016 Equity Incentive Plan (the "2016 Plan") and awards outstanding under the 2016 Plan became awards for common stock. Effective as of the Merger, no further awards may be issued under the 2016 Plan.

On July 28, 2019, the Compensation Committee of the Board of Directors (the "Compensation Committee") of the Company adopted the Seelos Therapeutics, Inc. 2019 Inducement Plan (the "2019 Inducement Plan"), which became effective on August 12, 2019. The 2019 Inducement Plan is substantially similar to the 2016 Plan. 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. The 2019 Inducement Plan is administered by the Compensation Committee and expires on August 12, 2029.

Stock options

During the year ended December 31, 2019, the Company granted 341,035 incentive stock options to employees with a weighted average exercise price per share of $2.03 and a 10-year term, subject to the terms and conditions of the 2012 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, 2019, the Company also granted 136,000 non-qualified stock options to non-employee directors with a weighted average exercise price per share of $2.33 and a 10-year term, subject to the terms and conditions of the 2012 Plan above. 72,000 of the stock options granted to non-employee directors vest 1/3rd on the first anniversary of the grant and monthly thereafter over the next two years. 64,000 of 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 the historical volatility of a publicly traded set of peer companies. 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, 2019, no stock options were exercised or forfeited.

The following assumptions were used in determining the fair value of the stock options granted during the year ended December 31, 2019:

	Year Ended December 31, 2019
Risk-free interest rate	1.6% - 2.6%
Volatility	109% - 113%
Dividend yield	-%
Expected term	5 - 6.97 years
Forfeiture rate	-%
Weighted average fair value	$1.76

Key assumptions used to estimate the fair value of non-employee stock options measured during the year ended December 31, 2018 included risk-free interest rates of 2.78% to 3.03%, an expected volatility of 54.0%, and no expected dividend yield. No options were issued during the year ended December 31, 2018.

A summary of stock option activity during the year ended December 31, 2019 is as follows (in thousands):

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Total Aggregate Intrinsic Value
Outstanding as of December 31, 2018	45	$ 84.66	7.7	$ 630
Granted	477	2.11	9.3	
Exercised	-	-		
Cancelled	-	-	-	
Outstanding as of December 31, 2019	522	$ 9.18	9.0	$ 21
Vested and expected to vest as of December 31, 2019	93	$ 42.01	8.0	$ 21
Exercisable as of December 31, 2019	93	$ 42.01	8.0	$ 21

The Company recorded $459,000 and $33,000 in stock-based compensation expense for the years ended December 31, 2019 and 2018, respectively.

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,	
	2019	2018
Research and development	$ 118	$ -
General and administrative	341	33
	$ 459	$ 33

9. Related Party Transactions

IRRAS AB ("IRRAS") is a commercial stage medical technology company of which a former director of the Company is also the President, Chief Executive Officer and director. In January 2018, the Company and IRRAS entered into a Sublease, pursuant to which the Company subleased to IRRAS excess capacity in its corporate headquarters. The sublease had a term of two years. On October 30, 2018, the Company and IRRAS entered into an amended and restated sublease, commencing January 1, 2019, pursuant to which the Company agreed to sublease to IRRAS the remainder of its San Diego, California location (the "IRRAS Restated Sublease"), which satisfied a closing condition related to the Merger. The IRRAS Restated Sublease has a term of one year and provides for aggregate payments due to the Company of approximately $0.4 million, which approximates fair value.

10. Income Taxes

The Company has incurred net operating losses since inception. At December 31, 2019, the Company had net operating loss carryforwards of approximately $244 million and $42 million for federal and State income tax purposes, respectively. As a result of the Merger, $ 226.8 million of federal net operating losses cannot be realized due to the substantial annual limitation on the utilization of net operating losses required by Internal Revenue Code Section 382. As such, the Company's deferred tax assets do not include the tax impact of these net operating loss carryforwards.

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

	December 31,	
	2019	2018
Net operating tax loss and capital loss carryforwards	$ 5,632	$ 1,042
Accrued expenses	348	21
Stock-based compensation	84	27
Start up cost	4,806	331
Total deferred tax asset	10,870	1,421
Less valuation allowance	(10,870)	(1,421)
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, 2019 and 2018 of approximately $17.7 million and $3.2 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.

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 2016 to 2019 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, 2019 and 2018, 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.

A reconciliation of the Company's unrecognized tax benefits for the years ended December 31, 2019 and 2018, are as follows (in thousands):

	Year Ended December 31,	
	2019	2018
Beginning balance	$ 718	$ 713
Change in current period positions	-	13
Change in prior period positions	(718)	(8)
Ending balance	$ -	$ 718

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, 2019 and 2018, are as follows:

	Year Ended December 31,	
	2019	2018
Federal statutory tax rate	21.0 %	21.0 %
State and local taxes, net of federal benefit	6.7 %	11.7 %
Permanent items	(9.0)%	(2.7)%
Prior year true-up	- %	(1.4)%
Other	(0.3)%	- %
Change in valuation allowance	(18.4)%	(28.6)%
Income tax provision (benefit)	- %	- %

11. 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. The rental agreement contains a base rent of approximately $9,000 per month.

In December 2011, Apricus entered into a five-year lease agreement for its original headquarters in San Diego, California expiring December 31, 2016. In December 2015, Apricus amended the lease agreement to extend the term through January 31, 2020. The Company had an option to extend the lease an additional three years. The original lease term contained a base rent of approximately $24,000 per month with 3% annual escalations, plus a supplemental real estate tax and operating expense charge to be determined annually. The Company elected to not renew this lease in January 2020.

For the years ended December 31, 2019 and 2018, rent expense totaled $0.1 million and $0, respectively.

Future minimum rental payments under operating leases as of December 31, 2019 are approximately $33,000 for 2020.

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, 2019, there was no material litigation against the Company.

12. Subsequent Events

Stock Purchase Agreement

On January 2, 2020, the Company entered into a stock purchase agreement (the "Stock Purchase Agreement") with Vyera, pursuant to which the Company issued to Vyera 1,809,845 registered shares of the Company's common stock (the "Shares"). The Company entered into the Stock Purchase Agreement in accordance with the Vyera Agreement, as amended by the Amendment. As partial consideration for the Vyera Assets, the Company agreed to issue the Shares pursuant to the Stock Purchase Agreement. The Shares were issued pursuant to the Company's registration statement on Form S-3 (File No. 333-221285), as amended, which was declared effective by the SEC on December 7, 2017, a base prospectus dated December 7, 2017 and a prospectus supplement dated January 2, 2020.

Public Offerings

On February 13, 2020, the Company completed an underwritten public offering pursuant to which the Company sold 6,666,667 shares of its common stock, at a price to the public of $0.75 per share. On February 19, 2020, the Company sold an additional 999,999 shares of its common stock at a price to the public of $0.75 per share pursuant to the full exercise of the underwriters' option to cover over-allotments. The net proceeds to the Company from the offering were approximately $5.0 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company.

On March 16, 2020, the Company completed an underwritten public offering pursuant to which the Company sold 7,500,000 shares of its common stock at a price to the public of $0.60 per share. The net proceeds to the Company from the offering were approximately $3.9 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company.

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"), who serves as the principal executive officer and the principal financial officer, 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, 2019. Based on this evaluation, our CEO concluded that our disclosure controls and procedures were effective as of December 31, 2019.

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, 2019 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, 2019, 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

Upon completion of the Merger, all remaining Apricus employees were terminated and all internal controls over financial reporting were assumed by the new accounting staff of STI and therefore, there were significant changes in our internal control structure over financial reporting during the year ended December 31, 2019.

ITEM 9B. OTHER INFORMATION

None

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, 2019 in connection with the Annual Meeting of Stockholders to be held in 2020 (the "2020 Proxy Statement"). To the extent that we do not file the 2020 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/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 2020 Proxy Statement. The 2020 Proxy Statement will be filed within 120 days after the end of the fiscal year ended December 31, 2019. To the extent that we do not file the 2020 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 2020 Proxy Statement. The 2020 Proxy Statement will be filed within 120 days after the end of the fiscal year ended December 31, 2019. To the extent that we do not file the 2020 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 2020 Proxy Statement. The 2020 Proxy Statement will be filed within 120 days after the end of the fiscal year ended December 31, 2019. To the extent that we do not file the 2020 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 2020 Proxy Statement. The 2020 Proxy Statement will be filed within 120 days after the end of the fiscal year ended December 31, 2019. To the extent that we do not file the 2020 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 October 17, 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).
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 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 February 12, 2015).
4.4	Form of Warrant issued to Sarissa Capital Domestic Fund LP and Sarissa Capital Offshore Master Fund LP (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 January 13, 2016).
4.5	Form of Warrant issued to other purchasers (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 January 13, 2016).
4.6	Form of Warrant Amendment (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 13, 2016).
4.7	Form of Warrant (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 28, 2016).

4.8	Form of Warrant (incorporated herein by reference to Exhibit 4.9 of Amendment No. 1 to Company's Registration Statement on Form S-1 (File No. 333-217036) filed with the Securities and Exchange Commission on April 17, 2017).
4.9	Form of Warrant Amendment (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 April 21, 2017).
4.10	Form of Warrant (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 11, 2017).
4.11	Form of Indenture (incorporated herein by reference to Exhibit 4.13 to the Company's Registration Statement on Form S-3 (File No. 333-221285) filed with the Securities and Exchange Commission on November 2, 2017).
4.12	Amendment to Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.12 of Amendment No. 1 to the Company's Registration Statement on Form S-3 (File No. 333-2223353) filed with the Securities and Exchange Commission on March 22, 2018).
4.13	Amendment to Warrant to Purchase Common Stock, dated as of March 27, 2018 (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 March 29, 2018).
4.14	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).
4.15	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).
4.16	Amendment to Warrant to Purchase Common Stock, dated as of June 22, 2018, by and between the Company and Sarissa Offshore (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 June 22, 2018).
4.17	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).
4.18	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).
4.19	Form of Registration Rights Agreement (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 September 21, 2018).
4.20	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).
4.21	Registration Rights Agreement, dated October 16, 2018, by and among the Company and certain investors named therein (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 17, 2018).

4.22	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).
4.23	Form of Series B Warrant, issued to investors on January 31, 2019 (incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 6, 2019).
4.24	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).
4.25*	Description of Securities of Seelos Therapeutics, Inc.
10.1#	2006 Stock Incentive Plan (incorporated herein by reference to Annex A of the Company's Definitive Proxy Statement filed with the Securities and Exchange Commission on April 6, 2006).
10.2#	Amendment to 2006 Stock Incentive Plan (incorporated herein by reference to Appendix A of the Company's Definitive Proxy Statement filed with the Securities and Exchange Commission on April 18, 2008).
10.3#	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).
10.4†	License Agreement and Amendment, by and between NexMed (U.S.A.), Inc. and Warner Chilcott Company, LLC, dated September 9, 2015 (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 5, 2015).
10.5	Subscription Agreement dated January 12, 2016, among the Company, Sarissa Capital Domestic Fund LP and Sarissa Capital Offshore Master Fund LP (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 January 13, 2016).
10.6#	Form of Restricted Stock Unit Award Agreement (incorporated herein by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 9, 2016).
10.7	Asset Purchase Agreement, dated March 8, 2017, by and between Ferring International Center S.A. and the Company, NexMed (U.S.A.), Inc., NexMed Holdings, Inc. and NexMed International 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 on March 8, 2017).
10.8	License Agreement, dated March 8, 2017, by and between the Company and Ferring International Center S.A. (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 March 8, 2017).
10.9	Form of Registration Rights Agreement (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 September 11, 2017).

10.10	Amendment No. 1 to Subscription Agreement, dated as of June 22, 2018, by and between the Investors and the Company (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 June 22, 2018).
10.11	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).
10.12	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).
10.13†	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).
10.14+†	Asset Purchase Agreement, dated as of March 6, 2018, by and between Seelos Therapeutics, Inc. and Vyera Pharmaceuticals AG f/k/a Turing Pharmaceuticals AG (incorporated by reference to Exhibit 10.34 of the Company's Registration Statement on Form S-4 filed on August 31, 2018).
10.15†	Amendment to Asset Purchase Agreement, dated as of May 18, 2018, by and between Seelos Therapeutics, Inc. and Vyera Pharmaceuticals AG f/k/a Turing Pharmaceuticals AG (incorporated by reference to Exhibit 10.35 of the Company's Registration Statement on Form S-4 filed on August 31, 2018).
10.16	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).
10.17#	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).
10.18#	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).
10.19	Form of Second Amendment Agreement, dated as of January 4, 2019, by and among Seelos Therapeutics, Inc., the Company and the investors party thereto (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 January 4, 2019).
10.20	Form of Third Amendment Agreement, dated as of January 16, 2019, by and among Seelos Therapeutics, Inc., the Company and the investors party thereto (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 January 16, 2019).
10.21#	Non-Employee Director Compensation Policy (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 March 26, 2019).
10.22#	Employment Agreement by and between the Company and Raj Mehra, Ph.D., dated March 20, 2019 (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 March 26, 2019).
10.23	Equity Distribution Agreement, dated as of June 17, 2019, by and between the Company and Piper Jaffray & Co. (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 on June 17, 2019).

10.24#	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).
10.25	Amendment No. 2 to Asset Purchase Agreement, dated as of December 31, 2018, by and between Seelos Therapeutics, Inc. and Phoenixus AG f/k/a Vyera Pharmaceuticals AG and Turing Pharmaceuticals AG. (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 7, 2019).
10.26#	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).
10.27^	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).
10.28	Amendment No. 3 to Asset Purchase Agreement, dated October 15, 2019, by and between Seelos Therapeutics, Inc. and Phoenixus AG (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 October 21, 2019).
10.29#	2012 Stock Long Term Incentive Plan, as amended and restated effective January 23, 2019 (incorporated herein by reference to Annex E to the Company's Registration Statement on Form S-4/A (File No. 333-217036), filed with the Securities and Exchange Commission on November 16, 2018).
10.30*	Amendment to License Agreement, dated as of February 8, 2019, by and among Ligand Pharmaceuticals Incorporated, Neurogen Corporation, CyDex Pharmaceuticals, Inc., and Seelos Corporation.
21.1	Subsidiaries (incorporated herein by reference to Exhibit 21.1 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 28, 2019).
23.1*	Consent of KPMG, LLP, independent registered public accounting firm.
31.1*	Certification of Principal Executive Officer and Principal Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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)

(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.

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 17, 2020

/s/ Raj Mehra, Ph.D.

Raj Mehra, Ph.D.

President and Chief Executive 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, Chairman of the Board and Interim Chief Financial Officer *(Principal Executive Officer, Principal Financial and Accounting Officer)*	March 17, 2020
/s/ Brian Lian, Ph.D. Brian Lian, Ph.D.	Director	March 17, 2020
/s/ Daniel J. O'Connor, J.D. Daniel J. O'Connor, J.D.	Director	March 17, 2020
/s/ Richard W. Pascoe Richard W. Pascoe	Director	March 17, 2020
/s/ Dr. Robin L. Smith Dr. Robin L. Smith	Director	March 17, 2020

Exhibit 4.25

DESCRIPTION OF SECURITIES OF SEELOS THERAPEUTICS, INC.

The authorized capital stock of Seelos Therapeutics, Inc., a Nevada corporation (the "***Company***"), consists of:

- 120,000,000 shares of common stock, $0.001 par value per share ("***Common Stock***"); and
- 10,000,000 shares of preferred stock, $0.001 par value per share ("***Preferred Stock***").

Common Stock

- ***Voting Rights***. Holders of Common Stock are entitled to one vote per share for the election of directors and on all other matters that require stockholder approval. Holders of Common Stock do not have any cumulative voting rights.
- ***Liquidation Rights***. Subject to any preferential rights of any outstanding Preferred Stock, in the event of the Company's liquidation, dissolution or winding up, holders of Common Stock are entitled to share ratably in the assets remaining after payment of liabilities and the liquidation preferences of any outstanding Preferred Stock.
- ***No Preemptive or Redemption Rights***. Shares of Common Stock do not carry any redemption rights or any preemptive or preferential rights enabling a holder to subscribe for, or receive shares of, any class of Common Stock or any other securities convertible into Common Stock.
- ***Dividend Rights***. Holders of Common Stock shall be entitled to receive dividends if, as and when declared by the Company's Board of Directors (the "***Board***") in accordance with applicable law.
- ***Anti-Takeover Provisions***. See the below section titled "Anti-Takeover Effects of Nevada Law and Provisions of the Company's Articles of Incorporation and Bylaws".

Listing

The Common Stock is listed on the Nasdaq Capital Market under the symbol "SEEL".

Preferred Stock

Under the Company's Amended and Restated Articles of Incorporation, as amended (the "***Articles of Incorporation***"), the Board has the authority, without further action by the stockholders, to designate one or more series of Preferred Stock and to fix the voting powers, designations, preferences, limitations, restrictions and relative rights granted to or imposed upon the Preferred Stock, including dividend rights, conversion rights, voting rights, rights and terms of redemption, liquidation preference and sinking fund terms. Any or all of these may be preferential to or greater than the rights of the Common Stock. Of the Company's authorized Preferred Stock, 1,000,000 shares have been designated as Series A Junior Participating Preferred Stock, 800 shares have been designated as Series B 8% Cumulative Convertible Preferred Stock and 600 shares have been designated as Series C 6% Cumulative Convertible Preferred Stock. The Company currently has no outstanding shares of Preferred Stock.

The Board may authorize the issuance of Preferred Stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of shares of Common Stock. The issuance of Preferred Stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of the Company and may adversely affect the market price of the Common Stock and the voting and other rights of the holders of shares of Common Stock.

The Board may specify the following characteristics of Preferred Stock:

- The designation and stated value, if any, of the class or series of Preferred Stock;
- The number of shares of the class or series of Preferred Stock offered, and the liquidation preference, if any, per share;
- the dividend rate(s), period(s) or payment date(s) or method(s) of calculation, if any, applicable to the class or series of Preferred Stock;
- whether dividends, if any, are cumulative or non-cumulative and, if cumulative, the date from which dividends on the class or series of Preferred Stock will accumulate;
- the provisions for a sinking fund, if any, for the class or series of Preferred Stock;
- the provision for redemption, if applicable, of the class or series of Preferred Stock;
- the terms and conditions, if applicable, upon which the class or series of Preferred Stock will be convertible into Common Stock, including the conversion price or manner of calculation and conversion period;
- voting rights, if any, of the class or series of Preferred Stock;
- the relative ranking and preferences of the class or series of Preferred Stock as to dividend rights and rights, if any, upon the liquidation, dissolution or winding up of the Company's affairs;
- any limitations on issuance of any class or series of Preferred Stock ranking senior to or on a parity with the class or series of Preferred Stock as to dividend rights and rights, if any, upon liquidation, dissolution or winding up of the Company's affairs; and
- any other specific terms, preferences, rights, limitations or restrictions of the class or series of Preferred Stock.

Warrants

As of December 31, 2019, the Company had outstanding warrants to purchase 3,583,713 shares of Common Stock as follows:

- warrants to purchase an aggregate of 12,642 shares with an exercise price of $18.00 per share, all of which are currently exercisable (subject to certain beneficial ownership limitations) and expire on March 13, 2020, all of which shall be automatically exercised on a "cashless" basis upon expiration if the fair market value of the Common Stock is greater than the exercise price of the warrants on the expiration date of the warrants;
- warrants to purchase an aggregate of 8,386 shares with an exercise price of $52.50 per share, all of which are currently exercisable (subject to certain beneficial ownership limitations) and expire on April 20, 2022, all of which shall be automatically exercised on a "cashless" basis upon expiration if the fair market value of the Common Stock is greater than the exercise price of the warrants on the expiration date of the warrants;

- warrants to purchase an aggregate of 81,587 shares with an exercise price of $46.50 per share, all of which are currently exercisable (subject to certain beneficial ownership limitations) and expire on May 17, 2022, all of which shall be automatically exercised on a "cashless" basis upon expiration if the fair market value of the Common Stock is greater than the exercise price of the warrants on the expiration date of the warrants;
- warrants to purchase an aggregate of 11,338 shares with an exercise price of $12.60 per share, all of which are currently exercisable and expire on January 12, 2023;
- a warrant to purchase an aggregate of 916 shares with an exercise price of $21.30 per share, all of which are currently exercisable and expire on January 12, 2023;
- warrants to purchase an aggregate of 2,037 shares with an exercise price of $21.30 per share, which are currently exercisable (subject to certain beneficial ownership limitations) and expire on January 12, 2023;
- warrants to purchase an aggregate of 3,647 shares with an exercise price of $21.30 per share, all of which are currently exercisable (subject to certain beneficial ownership limitations) and expire on March 3, 2023;
- warrants to purchase an aggregate of 11,081 shares with an exercise price of $12.60 per share, all of which are currently exercisable and expire on March 3, 2023;
- warrants to purchase an aggregate of 11,836 shares with an exercise price of $18.75 per share, all of which are currently exercisable (subject to certain beneficial ownership limitations) and expire on March 28, 2023;
- warrants to purchase an aggregate of 80,008 shares with an exercise price of $15.00 per share, all of which are currently exercisable (subject to certain beneficial ownership limitations) and expire on May 17, 2023;
- warrants to purchase an aggregate of 7,668 shares with an exercise price of $10.125 per share, all of which are currently exercisable (subject to certain beneficial ownership limitations) and expire on March 25, 2024, all of which shall be automatically exercised on a "cashless" basis upon expiration if the fair market value of the Common Stock is greater than the exercise price of the warrants on the expiration date of the warrants;
- warrants to purchase an aggregate of 646 shares with an exercise price of $387.00 per share, all of which are currently exercisable and expire on October 17, 2024, all of which shall be automatically exercised on a "cashless" basis upon expiration if the fair market value of the Common Stock is greater than the exercise price of the warrants on the expiration date of the warrants;
- warrants to purchase an aggregate of 510 shares with an exercise price of $492.00 per share, all of which are currently exercisable and expire on July 23, 2025, all of which shall be automatically exercised on a "cashless" basis upon expiration if the fair market value of the Common Stock is greater than the exercise price of the warrants on the expiration date of the warrants;
- a warrant to purchase an aggregate of 115,000 shares with an exercise price of $9.00 per share, which is currently exercisable (subject to certain beneficial ownership limitations) and expires on March 25, 2024, which shall be automatically exercised on a "cashless" basis upon expiration if the fair market value of the Common Stock is greater than the exercise price of the warrants on the expiration date of the warrant;

- a warrant to purchase an aggregate of 89,239 shares with an exercise price of $12.00 per share, which is currently exercisable and expires on March 25, 2024, which shall be automatically exercised on a "cashless" basis upon expiration if the fair market value of the Common Stock is greater than the exercise price of the warrants on the expiration date of the warrant;
- Series A warrants to purchase an aggregate of 909,672 shares with an exercise price of $0.75 per share, all of which are currently exercisable (subject to certain beneficial ownership limitations) and expire on January 31, 2024; and
- warrants to purchase an aggregate of 2,237,500 shares with an exercise price of $1.78 per share, which became exercisable on February 27, 2020 (subject to certain beneficial ownership limitations) and expire on August 28, 2023.

All of the outstanding warrants contain provisions for the adjustment of the exercise price in the event of stock dividends, stock splits or similar transactions. In addition, certain of the warrants contain a "cashless exercise" feature that allows the holders thereof to exercise the warrants without a cash payment to the Company under certain circumstances. Certain of the warrants also contain provisions that provide certain rights to warrantholders in the event of a fundamental transaction, including a merger or consolidation with or into another entity, such as:

- the right to receive the same amount and kind of consideration paid to the holders of Common Stock in the fundamental transaction;
- the right to require the Company or a successor entity to purchase the unexercised portion of certain warrants at the warrant's respective fair value using the Black Scholes option pricing formula; or
- the right to require the Company or a successor entity to redeem the unexercised portion of certain warrants for the same consideration paid to holders of Common Stock in the fundamental transaction at the warrant's respective fair value using the Black Scholes option pricing formula.

The Series A warrants provide that, from January 31, 2019 through January 31, 2022, inclusive, if the Company publicly announces, issues or sells, or is deemed to have issued or sold, any shares of Common Stock for a price per share less than the exercise price of the Series A warrants in effect immediately prior to such public announcement, issue or sale or deemed issuance or sale, subject to certain limited exceptions, then the exercise price of the Series A warrants shall be reduced to such lower price per share. If the Company publicly announces, issues or sells, or is deemed to have issued or sold any shares of Common Stock for a price per share lower than the exercise price of the Series A warrants then in effect after January 31, 2022, subject to certain limited exceptions, then the exercise price of the Series A warrants shall be reduced to an amount equal to the product of (i) the exercise price in effect immediately prior to such public announcement, issue or sale or deemed issuance or sale and (ii) the quotient determined by dividing (a) the sum of (x) the product derived by multiplying the exercise price then in effect and the number of shares of Common Stock outstanding immediately prior to the new issuance plus (y) the consideration received by the Company for the new issuance, by (b) the product derived by multiplying (x) the exercise price then in effect by (y) the number of shares of Common Stock outstanding immediately after the new issuance. Shares of Common Stock will be deemed to be issued or sold if the Company: (1) grants or sells, or publicly

announce the issuance or sale of, any options to purchase shares of Common Stock and the lowest price per share for which one share of Common Stock is issuable upon the exercise of such option (or upon conversion, exercise or exchange of any convertible security issuable upon exercise of such option) is less than the exercise price of the Series A warrant, or (2) issue or sell, or publicly announce the issuance or sale of, any convertible securities and the lowest price per share for which one share of Common Stock is issuable upon the conversion, exercise or exchange of such convertible security is less than the exercise price of the Series A warrant. The exercise price is subject to adjustment in accordance with the foregoing provisions and in the event of stock dividends, stock splits or similar transactions.

Anti-Takeover Effects of Nevada Law and Provisions of the Company's Articles of Incorporation and Bylaws

Certain provisions of Nevada law and the Articles of Incorporation, and the Company's Amended and Restated Bylaws, as amended (the "***Bylaws***"), could make the following more difficult:

- acquisition of the Company by means of a tender offer;
- acquisition of the Company by means of a proxy contest or otherwise; or
- removal of the Company's incumbent officers and directors.

These provisions, summarized below, could have the effect of discouraging certain types of coercive takeover practices and inadequate takeover bids. These provisions may also encourage persons seeking to acquire control of the Company to first negotiate with the Board.

Classified Board. The Articles of Incorporation provide that the Board is to be divided into three classes, as nearly equal in number as possible, with directors in each class serving three-year terms. This provision may have the effect of delaying or discouraging an acquisition of the Company or a change in the Company's management.

Filling Vacancies. The Articles of Incorporation provide that newly created directorships resulting from any increase in the authorized number of directors or any vacancies in the Board resulting from death, resignation, retirement, disqualification, removal from office or other cause shall, unless otherwise provided by law or resolution of the Board, be filled only by a majority of the directors then in office, though less than a quorum. The directors so chosen shall hold office for a term expiring at the annual meeting of stockholders at which the term of office of the class to which they have been chosen expires.

Removal. The Bylaws and the Nevada Revised Statutes ("***NRS***") provide that any director may be removed from the Board by the vote or written consent of stockholders representing not less than two-thirds of the voting power of the issued and outstanding shares entitled to vote.

Requirements for Advance Notification of Stockholder Nominations and Proposals. The Bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the Board.

Special Meetings of the Stockholders. The Bylaws provide that special meetings of the stockholders may be called by the Chair of the Board or the Company's President, or by the Board acting pursuant to a resolution adopted by the total number of authorized directors, whether or not there exist any vacancies in previously authorized directorships.

No Cumulative Voting. The Articles of Incorporation and the Bylaws do not provide for cumulative voting in the election of directors.

Undesignated Preferred Stock. The authorization of undesignated Preferred Stock in the Articles of Incorporation makes it possible for the Board to issue Preferred Stock with voting or other rights or preferences that could impede the success of any attempt to change control of the Company. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of the Company.

Amendment of Charter Provisions. The amendment of any of the above provisions set forth in the Articles of Incorporation, except for the provision making it possible for the Board to issue undesignated Preferred Stock, would require approval by a stockholder vote by the holders of at least 66-2/3% of the voting power of all the then-outstanding shares of the capital stock of the Company entitled to vote generally in the election of directors.

In addition, the NRS contain provisions governing the acquisition of a controlling interest in certain Nevada corporations. Nevada's "acquisition of controlling interest" statutes (NRS 78.378 through 78.3793, inclusive) 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 laws will apply to the Company as of a particular date if the Company were to have 200 or more stockholders of record (at least 100 of whom have addresses in Nevada appearing on the Company's stock ledger at all times during the 90 days immediately preceding that date) and do business in the State of Nevada directly or through an affiliated corporation, unless the Company's articles of incorporation or bylaws in effect on the tenth day after the acquisition of a controlling interest provide otherwise. These laws 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 which 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. These laws may have a chilling effect on certain transactions if the Articles of Incorporation or Bylaws are not amended to provide that these provisions do not apply to the Company or to an acquisition of a controlling interest, or if the Company's disinterested stockholders do not confer voting rights in the control shares.

Nevada's "combinations with interested stockholders" statutes (NRS 78.411 through 78.444, inclusive) provide that specified types of business "combinations" between certain Nevada corporations and any person deemed to be an "interested stockholder" of the corporation are prohibited for two years after such person first becomes an "interested stockholder" unless the corporation's board of directors approves the combination (or the transaction by which such person becomes an "interested stockholder") in advance, or unless the combination is approved by the board of directors and sixty percent of the corporation's voting power not beneficially owned by the interested stockholder, its affiliates and associates. Furthermore, in the absence of prior approval, certain restrictions may apply even after such two-year period. For purposes of these statutes, an "interested stockholder" is any person who is (1) the beneficial owner, directly or indirectly, of 10% or more of the voting power of the outstanding voting shares of the corporation, or (2) an affiliate or associate of the corporation and at any time within the two previous years was the beneficial owner, directly or indirectly, of 10% or more of the voting power of the then-outstanding shares of the corporation. The definition of the term "combination" is sufficiently broad to cover most significant transactions between a corporation and an "interested stockholder". These laws generally apply to Nevada corporations with 200 or more stockholders of record. However, a Nevada corporation may elect in its articles of incorporation not to be governed by these particular laws, but if such election is not made in the corporation's original articles of incorporation, the amendment (1) must be approved by the affirmative vote of the holders of stock representing a majority of the outstanding voting power of the corporation not beneficially owned by interested stockholders or their affiliates and associates, and (2) is not effective until 18 months after the vote approving the amendment and does not apply to any combination with a person who first became an interested stockholder on or before the effective date of the amendment. The Company has not made such an election in its original articles of incorporation or in its Articles of Incorporation and the Company has not amended its Articles of Incorporation to so elect.

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).

Exhibit 10.30

AMENDMENT TO LICENSE AGREEMENT

This Amendment to License Agreement (this "**Amendment**") is made and entered into as of February 8, 2019, by and among Ligand Pharmaceuticals Incorporated, a Delaware corporation ("**Ligand**"), Neurogen Corporation, a Delaware corporation ("**Neurogen**"), CyDex Pharmaceuticals, Inc., a Delaware corporation ("**CyDex**"), and Seelos Corporation, formerly known as Seelos Therapeutics, Inc., a Delaware corporation ("**Seelos**"). This Amendment amends that certain License Agreement dated as of September 21, 2016 by and among Ligand, Neurogen, CyDex and Seelos (including all amendments, if any, before the date of this Amendment, the "**Agreement**"). Capitalized terms not otherwise defined in this Amendment shall have the meanings ascribed to them in the Agreement.

RECITALS:

WHEREAS, Ligand, Neurogen, CyDex and Seelos are parties to the Agreement;

WHEREAS, Section 13.5 of the Agreement provides, among other things, that no modification or amendment of any provision of the Agreement shall be valid or effective unless made in a writing referencing the Agreement and signed by a duly authorized officer of each Party; and

WHEREAS, Ligand, Neurogen, CyDex and Seelos desire to amend the Agreement as set forth herein.

NOW, THEREFORE, in consideration of the foregoing and of the various promises and undertakings set forth herein, the Parties agree as follows:

1. Upfront Fee Timing. Section 5.1(b) of the Agreement is hereby amended to change the words "30 days" therein to "60 days".

2. Upfront Fee Settlement. Section 5.1(d) of the Agreement is hereby amended and restated in its entirety to read as follows:

> "(d) The Section 5.1(b)(i)-(iv) upfront payment amounts shall be payable by Seelos (i) in cash, (ii) in shares of the common stock of Seelos Therapeutics, Inc., a Nevada corporation, at a price per share of $3.25 (as adjusted for any stock dividend, stock split, stock combination, reclassification or similar transaction occurring after February 8, 2019), rounded down to the nearest whole share, or (iii) by a combination of such two methods, all as determined by Seelos at the time in Seelos' sole and absolute discretion."

3. Financing Milestone Payments Settlement. Section 5.2(d) of the Agreement is hereby amended and restated in its entirety to read as follows:

> "(d) The Section 5.2 financing milestone payment amounts shall be payable by Seelos (i) in cash, (ii) in shares of the common stock of Seelos Therapeutics, Inc., a Nevada corporation, at a price per share of $4.00 (as adjusted for any stock dividend, stock split, stock combination, reclassification or similar transaction occurring after February 8, 2019), rounded down to the nearest whole share, or (iii) by a combination of such methods set forth in subsections (i) and (ii), all as determined by Seelos at the time in Seelos' sole discretion."

4. Financing Milestone Payments Timing. Section 5.2(e) of the Agreement is hereby amended to change the words "30 days" therein to "60 days".

5. Full Force and Effect. Except as expressly set forth herein, the Agreement remains unchanged and in full force and effect. This Amendment shall be deemed an amendment to the Agreement and shall become effective when executed and delivered by the Parties. Upon the effectiveness of this Amendment, all references in the Agreement to "the Agreement" or "this Agreement," as applicable, shall refer to the Agreement, as modified by this Amendment.

6. Governing Law. This Amendment shall be governed by and interpreted in accordance with the laws of the State of New York, excluding application of any conflict of laws principles.

7. Counterparts. This Amendment may be executed in counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. A portable document format (PDF) copy of this Amendment, including the signature pages, will be deemed an original.

[Signature Page Follows]

IN WITNESS WHEREOF, Ligand, Neurogen, CyDex and Seelos have caused this Amendment to License Agreement to be executed as of the date first written above.

LIGAND PHARMACEUTICALS INCORPORATED

By: /s/ Matthew Korenberg
Name: Matthew Korenberg
Title: EVP & CFO

NEUROGEN CORPORATION

By: /s/ Matthew Korenberg
Name: Matthew Korenberg
Title: EVP & CFO

CYDEX PHARMACEUTICALS, INC.

By: /s/ Matthew Korenberg
Name: Matthew Korenberg
Title: EVP & CFO

SEELOS CORPORATION

By: /s/ Raj Mehra, Ph.D.
Name: Raj Mehra, Ph.D.
Title: Chief Executive Officer

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Seelos Therapeutics, Inc.:

We consent to the incorporation by reference in the registration statement (No. 333-234812) on Form S-1, registration statement (Nos. 333-229491, 333-229490, 333-223353, 333-221285, 333-220624, 333-220087, 333-200799, 333-198066, 333-191679, 333-182703, 333-178592, 333-165958, 333-152591, 333-148060, 333-140110, 333-132611, 333-125565, 333-122114, 333-117717, 333-111894, 333-107137, 333-105509, 333-96813, 333-46976 and 333-91957) on Form S-3 and registration statement (Nos. 333-233305, 333-229846, 333-218368, 333-215419, 333-210040, 333-204748, 333-191680, 333-182704, 333-152284, 333-138598, 333-174392, 333-167365 and 333-93435) on Form S-8 of Seelos Therapeutics, Inc. of our report dated March 17, 2020, with respect to the consolidated balance sheets of Seelos Therapeutics, Inc. as of December 31, 2019 and 2018, and the related 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, 2019, and the related notes, which report appears in the December 31, 2019 annual report on Form 10-K of Seelos Therapeutics, Inc.

Our report dated March 17, 2020 contains an explanatory paragraph that states that Seelos Therapeutics, Inc. has suffered recurring losses from operations and has a net capital deficiency, which raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty.

/s/ KPMG LLP

Short Hills, New Jersey
March 17, 2020

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND INTERIM CHIEF FINANCIAL OFFICER

I, Raj Mehra, Ph.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of Seelos Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)), and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 17, 2020

/S/ Raj Mehra, Ph.D.

Raj Mehra, Ph.D.

Chief Executive Officer, President and Interim Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND INTERIM CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Raj Mehra, Ph.D., certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report on Form 10-K of Seelos Therapeutics, Inc. for the year ended December 31, 2019 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents, in all material respects, the financial condition and results of operations of Seelos Therapeutics, Inc.

Date: March 17, 2020

By: /S/ Raj Mehra, Ph.D.

Name: Raj Mehra, Ph.D.

Title: Chief Executive Officer, President and Interim Chief Financial Officer