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, 2018

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) 998-6475
(Registrant's telephone number, including area code)

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

(Title of Class)	**(Name of exchange on which registered)**
Common Stock, par value $0.001 per share	**The Nasdaq Capital Market**

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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 March 14, 2019, 18,406,019 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: $9.1 million based upon the closing sale price of our common stock of $11.70 on that date. Common stock held by each officer and director and by each person known to own in excess of 10% of outstanding shares of our common stock has been excluded in that such persons may be deemed to be affiliates. The determination of affiliate status in not necessarily a conclusive determination for other purposes.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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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, and Section 21E of the Securities Exchange Act of 1934, as amended. 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," the Seelos logo, "Vitaros," and "RayVa" 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 developing novel technologies and therapeutics for the treatment of central nervous system, respiratory and other disorders.

Merger

On January 24, 2019, Apricus Biosciences, Inc. completed a reverse merger transaction (the "Merger") with Seelos Therapeutics, Inc., a Delaware corporation (now known as Seelos Corporation) ("STI"). Upon completion of the Merger, we changed our name to Seelos Therapeutics, Inc. and will focus on the development and commercialization of CNS therapeutics with known mechanisms of action in areas with a highly unmet medical need. 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. 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"). Accordingly, all share and per share information in this Annual Report on Form 10-K has been restated to retroactively show the effect of the Reverse Stock Split. Our previous ticker symbol was "APRI". Following the completion of the Merger, our business became primarily the business conducted by STI, which is a clinical-stage biopharmaceutical company focused on the development and advancement of novel therapeutics to address unmet medical needs for the benefit of patients with central nervous system disorders. See note 2 to our consolidated financial statements for more information regarding the Merger.

New 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 SLS-002, SLS-005 and SLS-006.

SLS-002 is intranasal racemic ketamine with two investigational new drug applications ("INDs"), for the treatment of suicidality in post-traumatic stress disorder ("PTSD"), and in major depressive disorder. 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. 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 an end-of-phase II meeting with the U.S. Food and Drug Administration ("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. Furthermore, the 12-month prevalence of attempted suicide in individuals with PTSD is approximately 400,000 in the U.S. based on the published literature. Experimental studies suggest ketamine to be a rapid, effective treatment for refractory depression and suicidality.

SLS-005, is Trehalose, a protein stabilizer that also activates autophagy and crosses the blood-brain-barrier. 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 2 clinical development for oculopharyngeal muscular dystrophy (OPMD) and spinocerebellar ataxia type 3, also known as Machado Joseph disease, with encouraging safety and efficacy results thus far. These pathological proteins aggregate within cells, eventually leading to cell death. Prior preclinical studies indicate that this platform has the potential to prevent mutant protein aggregation in other devastating PolyA/PolyQ diseases.

Two U.S. patents for parental administration of trehalose exist for patients with OPMD and SCA3; both 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 Team Sanfilippo Foundation (TSF), a nonprofit medical research foundation founded by parents of children with Sanfilippo syndrome. TSF, upon approval by the FDA, plans to begin an open label, Phase 2(b) clinical trial in up to 20 patients with Sanfilippo syndrome and we will provide the clinical supply of Trehalose. The terms of our agreement with TSF entitle us access to all clinical data from this trial.

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 Parkinson's disease patients and an attractive safety profile. Moreover, it has also shown synergistic effect with reduced doses of L-DOPA. We are planning to advance the product candidate into late stage trials as a monotherapy in early stage Parkinson's disease patients and as an adjunctive therapy with reduced doses of L-DOPA in late stage Parkinson's disease patients after consultation with and approval from the FDA and the European Medicines Agency ("EMA"). We believe that this Phase III-ready candidate is well-positioned to advance in development with a goal of providing relief to an estimated 1.5 million Parkinson's disease patients worldwide.

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

SLS-007, a peptide-based approach, targeting the NACore (nonamyloid component core). Recent in-vitro and cell culture research have shown the ability to stop the propagation and seeding of α-synuclein aggregates against increased monomeric alpha-synuclein expression, fibril preparations of seeded alpha-synuclein, and alpha-synuclein seeds derived from patients diagnosed with Parkinson's disease or Lewy Body Dementia. We will evaluate the potential for in-vivo delivery of SLS-007 in a Parkinson's disease transgenic mice model. The goal will be to establish in-vivo PK/PD and target engagement parameters of SLS-007, a family of anti-alpha-synuclein peptidic inhibitors.

SLS-008, an orally available antagonist for Chemoattractant Receptor-homologous molecule expressed on TH2 cells ("CRTh2"), targeted at chronic inflammation in asthma and orphan indications such as pediatric esophagitis. We have a "family" of compounds under its SLS-008 program. We intend to file an IND upon completing the IND-enabling studies in an undisclosed pediatric orphan indication where there is a high unmet need for an effective oral therapy.

SLS-010, an oral histamine H3A receptor antagonist that shows promising activity in narcolepsy and related disorders.

SLS-012, an injectable therapy for post-operative pain management.

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 PTSD and in major depressive disorder;
- Advancing SLS-006 in early stage and late stage Parkinson's disease as a monotherapy and adjunctive therapy, respectively;
- Filing an IND for SLS-008 in pediatric esophagitis and another undisclosed indication;
- Forming strategic collaborations in the European Union and Asian markets; and
- Acquiring synergistic assets in the central nervous system therapy space through licensing and partnerships.

Bioblast Asset Purchase

On February 15, 2019, we entered into an Asset Purchase Agreement (the "Bioblast Asset Purchase Agreement") with Bioblast Pharma Ltd. ("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 2(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 United States Food and Drug Administration or the Health Products and Food Branch of Health Canada of the first new drug application ("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 Team Sanfilippo Foundation ("TSF"), a nonprofit medical research foundation founded by parents of children with Sanfilippo syndrome. TSF, upon approval by the FDA, plans to begin an open label, Phase 2(b) clinical trial in up to 20 patients with Sanfilippo syndrome, which is now known under the study name SLS-005. Seelos will provide the clinical supply of Trehalose. The terms of the Bioblast Asset Purchase Agreement entitle Seelos access to all clinical data from this trial.

Asset Purchase Agreement with Vyera Pharmaceuticals AG

On March 6, 2018, STI entered into an Asset Purchase Agreement with Vyera Pharmaceuticals AG ("Vyera"), as amended by an amendment thereto entered into on May 18, 2018 (the "First Vyera Amendment") and an amendment thereto entered into on December 31, 2018 (the "Second Vyera Amendment" such agreement, as amended by the First Vyera Amendment and the Second Vyera Amendment, the "Vyera Asset Purchase Agreement"). Pursuant to the Vyera Asset Purchase Agreement, STI 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 now known as SLS-002. STI is obligated to use commercially reasonable efforts to seek regulatory approval in the United States for and commercialize SLS-002. STI 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 STI must commence a Phase III clinical trial for SLS-002 by the date 18 months from the closing of the transactions contemplated by the Vyera Asset Purchase Agreement (the "Vyera Closing"), and if STI fails to do so, the Vyera Asset Purchase Agreement will terminate immediately and become null and void and all of the Vyera Assets and the Vyera Assumed Liabilities will automatically be returned to Vyera.

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

As partial consideration for the Vyera Assets, upon execution of the First Vyera Amendment, STI paid to Vyera a non-refundable cash payment of $150,000. As further partial consideration for the Vyera Assets, upon public announcement of the entry by us and STI into the Merger Agreement, STI paid to Vyera a non-refundable cash payment of $150,000.

As further partial consideration for the Vyera Assets, upon the Vyera Closing, STI issued to Vyera 248,615 shares of STI's common stock and on January 25, 2019, we paid to Vyera cash consideration of $1.0 million. As further partial consideration for the Vyera Assets, STI 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 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. STI will also pay to Vyera royalty percentage in the mid-teens on aggregate annual net sales of SLS-002.

License Agreement with Ligand Pharmaceuticals Incorporated

On September 21, 2016, STI 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 STI 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. STI is obligated to use commercially reasonable efforts to (a) develop the Licensed Products, (b) obtain regulatory approval for the Licensed Products in the United States, 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 of which is referred to as a Major Market, and (c) commercialize the Licensed Products in each country where regulatory approval is obtained. STI 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 STI believes appropriate to obtain regulatory approvals for commercialization of the Licensed Products. STI also has 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, STI paid to Ligand a nominal option fee. As further partial consideration for the grant of the rights and licenses to STI under the License Agreement, STI is obligated pay to Ligand an aggregate of $1.3 million within 30 days after the closing of the issuance and sale by STI of debt and/or equity securities for gross proceeds to STI of at least $7.5 million. As further partial consideration for the grant of the rights and licenses to STI by Ligand under the License Agreement, STI 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 STI's initial public offering or a financing transaction consummated in connection with a transaction as a result of which STI's business becomes owned or controlled by an existing issuer with a class of securities registered under the Securities Exchange Act of 1934, as amended, and immediately after such transaction, the security holders of STI 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 STI in the event STI is acquired.

As further partial consideration for the grant of the rights and licenses to under the License Agreement, STI 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 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 to under the License Agreement, STI 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 Parkinson's disease 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, STI 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.

STI 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 Parkinson's disease 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 Parkinson's disease or Restless Leg Syndrome in a country where such Licensed Products are covered under a licensed patent. Additionally, STI 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 Parkinson's disease 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 Parkinson's disease or Restless Leg Syndrome in a country where such Licensed Products are not covered under a licensed patent.

UCLA Exclusive License

We acquired an exclusive license to intellectual property owned by The Regents of the University of California relating to a family of rationally-designed peptide inhibitors that target the aggregation of alpha-synuclein (α-synuclein). Seelos plans to study this initial approach in Parkinson's disease and will further evaluate the potential clinical approach in other disorders affecting the central nervous system. Pursuant to the terms of the license, we paid an up-front license fee and agreed to pay certain annual fees, as well as a low single-digit royalty on net sales of licensed products.

Legacy Pre-Merger Programs

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 product candidates: Vitaros, a product candidate in the United States for the treatment of erectile dysfunction ("ED"), which we in-licensed from Warner Chilcott Company, Inc., now a subsidiary of Allergan plc ("Allergan"); and RayVa, a product candidate which has completed a Phase 2a clinical trial for the treatment of Raynaud's Phenomenon, secondary to scleroderma, for which we own worldwide rights.

Vitaros (alprostadil) 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 Vitaros. 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 3 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. Vitaros rights to enable Vitaros' continued development and potential approval in exchange for financial terms commensurate with a development stage asset.

On March 8, 2017, we entered into an asset purchase agreement with Ferring (the "Ferring Asset Purchase Agreement"), pursuant to which we sold to Ferring our assets and rights related to 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 Vitaros 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 Vitaros 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 Vitaros 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 Vitaros. 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 Vitaros NDA, 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 Vitaros NDA 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 Vitaros 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 3 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 3 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.

RayVa is our product candidate 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. RayVa 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. RayVa received authorization in May 2014 from the FDA to begin clinical studies. We reported results from our Phase 2a clinical trial of RayVa 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 Vitaros will affect RayVa's future development path 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 Vitaros raised in the 2018 CRL may impact future development activities for other product candidates utilizing NexACT

technology. The safety concerns raised were specific to Vitaros 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.

Ferring Asset Purchase Agreement

On March 8, 2017, we entered into the Ferring Asset Purchase Agreement, pursuant to which, and on the terms and subject to the conditions thereof, among other things, we agreed to sell to Ferring our assets and rights (the "Purchased Assets") related to the business of developing, marketing, distributing, and commercializing, outside the United States, our products currently marketed or in development, intended for the topical treatment of sexual dysfunction (the "Product Business"), including products sold under the name Vitaros (the "Products"). The Purchased Assets include, among other things, certain pending and registered patents and trademarks, contracts, manufacturing equipment and regulatory approvals relating to the Products outside of the United States. We are retaining the U.S. development and commercialization rights for Vitaros and will receive a license from Ferring (the "Ferring License") for intellectual property rights for Vitaros and other products which relate to development both within the United States and internationally.

Pursuant to the terms of the Ferring Asset Purchase Agreement, we sold to Ferring our assets and rights related to 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.

As of the closing, which occurred on March 8, 2017, Ferring assumed responsibility for our obligations under the purchased contracts and regulatory approvals, as well as other liabilities associated with the Purchased Assets arising after the closing date. We retained all liabilities associated with the Purchased Assets arising prior to the closing date.

Under the Ferring Asset Purchase Agreement, we have also agreed to indemnify Ferring for, among other things, breaches of our representations, warranties and covenants, any liability for which we remain responsible and our failure to pay certain taxes or comply with certain laws, subject to a specified deductible in certain cases. Our aggregate liability under such indemnification claims is generally limited to $2.0 million.

At the closing of the Ferring Asset Purchase Agreement, we entered into the Ferring License with respect to certain intellectual property rights necessary to or useful for our exploitation of the Purchased Assets within the United States and for our exploitation of the Purchased Assets in certain fields outside of sexual dysfunction, including for the treatment of Raynaud's Phenomenon, outside the United States. The parties granted one another a royalty-free, perpetual and non-exclusive license to product know-how in their respective territories and Ferring granted us a royalty-free, perpetual and exclusive license to certain patents in the field of sexual dysfunction in the United States and in certain fields other than sexual dysfunction outside of the United States.

Patent Portfolio

As of March 14, 2019, we owned or in-licensed approximately 148 issued patents, which will expire from 2019 through 2032, approximately. Also, as of that same date, we owned or in-licensed approximately 30 patent applications, which if ultimately issued would expire as late as approximately 2032, based upon the potential expiration date of the last to expire of those patent applications. As to the in-licensed patents and patent applications, they include 129 issued patents and 18 patent applications from Ferring pursuant to the Ferring License.

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 March 14, 2019, 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," the Seelos logo, "Vitaros," and "RayVa" 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 1. Phase 1 includes the initial introduction of an investigational new drug into humans. Phase 1 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 1 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 2 clinical trials. The total number of participants included in Phase 1 clinical trials varies, but is generally in the range of 20 to 80.
- Phase 2. Phase 2 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 2 clinical trials are typically well-controlled, closely monitored, and conducted in a limited patient population, usually involving no more than several hundred participants.

- Phase 3. Phase 3 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 3 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 3 studies but may be Phase 2 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 API 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 3 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 4 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 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 European Union 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 European Union, 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 European Union ("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 28 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 European Union country of medicinal products that have not yet been authorized in any European Union country and that do not fall within the mandatory scope of the centralized procedure. 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 European Union Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other European Union countries in a procedure whereby the countries 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 European Union 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 European Union'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 March 14, 2019, we had 5 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.

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 under new management 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 will not change as a result of the merger. All of our therapeutic candidates are in the clinical development stage and none of our new 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 not generated any revenues from collaboration and licensing agreements or 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 never been profitable and have incurred an accumulated deficit of $325.2 million from our inception through December 31, 2018.

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 regulatory approvals for our product candidates and begins 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.

Prior to the merger, STI spent significant time, money and effort on the licensing and development of its core assets, SLS-002 and SLS-006 and its other earlier-stage assets, 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 new 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 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-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 3 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., 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 or 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, 2018, we had a cash balance of approximately $3.6 million.

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, 2018 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 under which we may offer from time to time any combination of debt securities, common and preferred stock and warrants. Under current SEC regulations, at any time during which 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 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 March 14, 2019, our public float was approximately $124.1 million based on 15.3 million shares of our common stock outstanding at a price of $8.1008 per share, which was the closing sale price of our common stock on January 15, 2019. While our public float was greater than $75.0 million as of March 14, 2019, there is no guarantee that this will continue to be the case, and if our public float were to fall below $75.0 million, we would be 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. 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.

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 or mood stabilizer. These antipsychotic compounds, such as AstraZeneca plc's Seroquel (quetiapine) and Bristol-Myers Squibb Company's Abilify (aripiprazole), and mood stabilizers, such as Janssen Pharmaceutica's Topamax (topiramate). In addition, Janssen's intranasal esketamine has recently shown a successful Phase III study in treatment-resistant depression and along with Allergan's rapastinel (formerly Naurex), both of which target the NMDA receptor and are expected to have a faster onset of therapeutic effect as compared to currently available therapies.

Current treatments for Parkinson's disease are intended to improve the symptoms of patients. The cornerstone of Parkinson's therapy is levodopa, as it is the most effective therapy for reducing symptoms of Parkinson's disease. There are other drug therapies in development that will target the disease, such as gene and stem cell therapy and A2A receptor agonists. Currently, the majority of products in development for Parkinson's disease are still in the pre-clinical stage.

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-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 Seelos, 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, 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 is 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 Seelos' 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 Seelos 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 has indicated its intent to withdraw from the European Union in the future. A significant portion of the regulatory framework in the United Kingdom is derived from the regulations of the European Union, and the EMA is currently located in the United Kingdom. We cannot predict what consequences the withdrawal of the United Kingdom from the European Union, if it occurs, 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, it 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 March 14, 2019, we have 5 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 officers do not have experience in managing and operating a public company, which could have an adverse effect on their ability to quickly respond to problems or adequately address issues and matters applicable to public companies. Any failure to comply with federal securities laws, rules or regulations could subject us to fines or regulatory actions, which may materially adversely affect our business, financial condition and results of operations. Further, since our executive officers do 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.

Because we do not currently have any clinical trials ongoing, we do not currently carry product liability insurance. We anticipate obtaining such insurance upon initiation of our clinical development activities; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. 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, chemicals and various radioactive compounds, 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 our contracts 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 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.

STI's license agreement with Ligand Pharmaceuticals Incorporated, Neurogen Corporation and CyDex Pharmaceuticals, Inc. (the "License Agreement") is important to our business and we expect to enter into additional license agreements in the future. The License Agreement imposes, 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 License Agreement, the licensors each have the right to terminate the 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 breaches the 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 License Agreement is terminated by a licensor, all licenses granted to us by such licensor will terminate immediately.

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 may be required to pay milestones and royalties pursuant to the License Agreement, which could adversely affect the overall profitability for us of any products that we may seek to commercialize.

Under the terms of the 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, we will be required to pay royalties to Vyera on net sales of SLS-002 pursuant to the Vyera Asset Purchase Agreement. These royalty payments could adversely affect the overall profitability for us of any products that we may seek to commercialize.

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

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

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;
- 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.

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 March 14, 2019, Dr. Mehra, our sole executive officer and a director, owns approximately 16.7% 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. Between February 27, 2019 and March 14, 2019, the holders of certain of our

outstanding warrants to purchase shares of our common stock elected to exercise such warrants resulting in the issuance of approximately 12.2 million shares of our common stock, which increased the number of shares of our common stock outstanding substantially. As of March 14, 2019, these investors continued to hold warrants to purchase approximately 3.1 million shares of our common stock, which, if exercised, would further increase the number of shares of our common stock outstanding.

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 STI and the investors listed on the Schedule of Buyers attached thereto, as amended (the "Financing SPA"), pursuant to which, among other things, we agreed to issue warrants to purchase shares of our common stock (the "Financing Warrants").

Certain of the Financing Warrants contain price-based adjustment provisions, pursuant to which the number of shares of our common stock that are issuable upon exercise of the Financing Warrants may be adjusted upward in the event of certain dilutive issuances by us. The circumstances under which the number of shares of our common stock issuable upon exercise of the Financing Warrants may be adjusted upward are set forth in the Financing Warrants.

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 14, 2019, the Financing Warrants were exercisable for approximately 3.1 million shares of our common stock. Sales of substantial numbers of such shares in the public market could depress the market price of our common stock. If the adjustment provisions in the Financing Warrants are triggered, a substantial number of additional shares of our common stock may become issuable upon exercise of the Financing Warrants, potentially increasing the impact of any subsequent exercise of the Financing Warrants and resale of the shares issuable pursuant thereto.

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 provides that directors of a Nevada corporation may resist a change or potential change in control if the board of directors determines that the change is opposed to, or not in, the best interests of the corporation.

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 two corporate office properties: (a) one in New York, as our new corporate office space and (b) one in San Diego for approximately 9,000 square feet. In January 2018, we and IRRAS AB ("IRRAS") entered into a Sublease, pursuant to which we subleased to IRRAS excess capacity in the San Diego property. Then, in October 30, 2018, we and IRRAS entered into an amended and restated sublease, commencing January 1, 2019, pursuant to which we agreed to sublease to IRRAS the remainder of the San Diego property. We believe that our leased facilities are generally well maintained and in good operating condition and that the New York 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." 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"). Accordingly, all share and per share information in this Report has been restated to retroactively show the effect of the Reverse Stock Split. 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 March 14, 2019, the last reported sales price for our common stock on the Nasdaq Capital Market was $2.78 per share, and we had approximately 108 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.

Equity Compensation Plan

The following table gives information as of December 31, 2018 about shares of our common stock that may be issued upon the exercise of options and restricted stock units under both of our existing equity compensation plans:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)(1)	Weighted-average exercise price of outstanding options, warrants and rights (b)(2)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)(3)
Equity compensation plans approved by security holders	38,416	$ 185.98	10,872

(1) Consists of options and restricted stock units outstanding as of December 31, 2018 under the 2012 Plan, and the 2006 Plan.
(2) Consists of the weighted average exercise price of outstanding options as of December 31, 2018.
(3) Consists entirely of shares of common stock that remain available for future issuance under the 2012 Plan as of December 31, 2018.

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

Disclosures Regarding Forward-Looking Statements

This report includes "forward-looking statements" within the meaning of Section 21E of the Exchange Act. Those statements include statements regarding the intent, belief or current expectations of Seelos Therapeutics, Inc. and 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 (the "SEC").

We have common law trademark rights in the unregistered marks "Seelos Therapeutics, Inc.," "Seelos," the Seelos logo, "Vitaros," and RayVa" in certain jurisdictions. Vitaros is a registered trademark of Ferring International Center S.A. ("Ferring") in certain countries outside of the United States. 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.

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, we completed a reverse merger transaction (the "Merger") with Seelos Therapeutics, Inc., a Delaware corporation (now known as Seelos Corporation) ("STI"). At the closing of the Merger, each outstanding share of STI's capital stock was converted into the right to receive 0.7704 shares of our common stock. Upon completion of the Merger, we changed our name to Seelos Therapeutics, Inc. and will focus on the development and commercialization of CNS therapeutics with known mechanisms of action in areas with a highly unmet medical need. 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"). Unless otherwise noted, references to share amounts, and other information have been adjusted to reflect 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".

The financial information included in this Management's Discussion and Analysis of Financial Condition and Results of Operations is that of Apricus Biosciences Inc. prior to the Merger because the Merger was consummated after the period covered by the financial statements included in this Annual Report. Accordingly, the historical financial information included in this Annual Report, unless otherwise indicated or as the context otherwise requires, is that of Apricus Biosciences Inc. prior to the Merger.

New Pipeline

We are planning on developing its clinical and regulatory strategy with its internal research and development team with a view toward prioritizing market introduction as quickly as possible. Our lead programs are SLS-002 and SLS-006.

SLS-002 is intranasal racemic ketamine with two investigational new drug applications ("INDs"), for the treatment of suicidality in post-traumatic stress disorder ("PTSD"), and in major depressive disorder. 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. 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 an end-of-phase II 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. Furthermore, the 12-month prevalence of attempted suicide in individuals with PTSD is approximately 400,000 in the U.S. based on the published literature. Experimental studies suggest ketamine to be a rapid, effective treatment for refractory depression and suicidality.

SLS-005, is Trehalose, a protein stabilizer that also activates autophagy and crosses the blood-brain-barrier. 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 2 clinical development for oculopharyngeal muscular dystrophy ("OPMD") and spinocerebellar ataxia type 3, also known as Machado Joseph disease ("SCA3"), with encouraging safety and efficacy results thus far. These pathological proteins aggregate within cells, eventually leading to cell death. Prior preclinical studies indicate that this platform has the potential to prevent mutant protein aggregation in other devastating PolyA/PolyQ diseases.

Two U.S. patents for parental administration of Trehalose exist for patients with OPMD and SCA3; both 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 Team Sanfilippo Foundation ("TSF"), a nonprofit medical research foundation founded by parents of children with Sanfilippo syndrome. TSF, upon approval by the FDA, plans to begin an open label, Phase 2(b) clinical trial in up to 20 patients with Sanfilippo syndrome and we will provide the clinical supply of Trehalose. The terms of our agreement with TSF entitle us to access to all clinical data from this trial.

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 Parkinson's disease patients and an attractive safety profile. Moreover, it has also shown synergistic effect with reduced doses of L-DOPA. We are planning to advance the product candidate into late stage trials as a monotherapy in early stage Parkinson's disease patients and as an adjunctive therapy with reduced doses of L-DOPA in late stage Parkinson's disease patients after consultation with and approval from the FDA and the EMA. We believe that this Phase III-ready candidate is well-positioned to advance in development with a goal of providing relief to an estimated 1.5 million Parkinson's disease patients worldwide.

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

SLS-007, a peptide-based approach, targeting the NACore (nonamyloid component core). Recent in-vitro and cell culture research have shown the ability to stop the propagation and seeding of α-synuclein aggregates against increased monomeric alpha-synuclein expression, fibril preparations of seeded alpha-synuclein, and alpha-synuclein seeds derived from patients diagnosed with Parkinson's disease or Lewy Body Dementia. We will evaluate the potential for in-vivo delivery of SLS-007 in a Parkinson's disease transgenic mice model. The goal will be to establish in-vivo PK/PD and target engagement parameters of SLS-007, a family of anti-alpha-synuclein peptidic inhibitors.

SLS-008, an orally available antagonist for Chemoattractant Receptor-homologous molecule expressed on TH2 cells ("CRTh2"), targeted at chronic inflammation in asthma and orphan indications such as pediatric esophagitis. We have a "family" of compounds under its SLS-008 program. We intend to file an IND in 2019 in an undisclosed pediatric orphan indication where there is a high unmet need for an effective oral therapy.

SLS-010, an oral histamine H3A receptor antagonist that shows promising activity in narcolepsy and related disorders.

SLS-012, an injectable therapy for post-operative pain management.

Pre-Merger Financing

On October 16, 2018, we entered into a Securities Purchase Agreement by and among the Company, STI, and the investors listed on the Schedule of Buyers attached thereto (the "Buyers"), as amended (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 our common stock and (ii) two series warrants to purchase shares of our common stock (the "Series A Warrants" and the "Series B Warrants" and together, the "Pre-Merger Warrants") for an aggregate purchase price of approximately $18.0 million.

We issued the Pre-Merger Warrants on January 31, 2019 and on February 14, 2019, we registered the resale of the 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 our common stock at an exercise price per share equal to $4.15, which was adjusted to 2,640,128 shares of our 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 our common stock at an exercise price per share equal to $1.6736 on March 7, 2019, in each case, pursuant to the terms thereof. 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 our common stock, which was adjusted to 7,951,090 shares of our common stock on February 27, 2019 and which was further adjusted to 11,614,483 shares of our common stock on March 7, 2019, in each case, pursuant to the terms thereof. The Series B Warrants have an exercise price of $0.001, were immediately exercisable upon issuance and will expire on the day following the later to occur of (i) the Reservation Date, 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.

Bioblast Asset Purchase

On February 15, 2019, we entered into an Asset Purchase Agreement (the "Bioblast Asset Purchase Agreement") with Bioblast Pharma Ltd. ("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"). Under the terms of the Bioblast Asset Purchase, we assumed a collaborative agreement with Team Sanfilippo Foundation ("TSF"), a nonprofit medical research foundation founded by parents of children with Sanfilippo syndrome. TSF, upon approval by the FDA, plans to begin an open label, Phase 2(b) clinical trial in up to 20 patients with Sanfilippo syndrome. We will provide the clinical supply of Trehalose. The terms of the Bioblast Asset Purchase Agreement entitle us access to all clinical data from this trial.

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 PTSD and in major depressive disorder;
- Advancing SLS-005 in Sanfilippo syndrome;
- Advancing SLS-007 in Parkinson's disease as a monotherapy
- Filing an IND for SLS-008 in pediatric esophagitis and another undisclosed indication;
- Forming strategic collaborations in the European Union 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: Vitaros, a product candidate in the United States for the treatment of erectile dysfunction ("ED"), which we in-licensed from Warner Chilcott Company, Inc., now a subsidiary of Allergan; and RayVa, a product candidate which has completed a Phase 2a clinical trial for the treatment of Raynaud's Phenomenon, secondary to scleroderma, for which we own worldwide rights.

Apricus Overview

As a result of the Merger, our historic business operations ceased and our going forward operations will be those of STI. Accordingly, the results of operations reported for the years ended December 31, 2018 and 2017, in this Management's Discussion and Analysis are not indicative of the results of operations expected in 2019 and future years due to the termination of our historic business operations.

As of December 31, 2018, we had an accumulated deficit of $325.2 million. We incurred a net loss of $9.2 million and net income of $0.3 million for the years ended December 31, 2018 and 2017, respectively.

Results of Operations

Operating Expense

Operating expense was as follows (in thousands, except percentages):

	Year Ended December 31,		2018 vs 2017	
	2018	2017	$ Change	% Change
Operating expense				
Research and development	$ 1,220	$ 3,463	$ (2,243)	-65%
General and administrative	7,928	7,210	718	10%
Loss on disposal of assets	-	2	(2)	-100%
Total operating expense	$ 9,148	$ 10,675	$ (1,527)	-14%

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 $2.2 million decrease in R&D expense during the year ended December 31, 2018 as compared to the prior year, resulted primarily from decreases in salary-related expenses and decreases in development expenses for U.S. Vitaros upon completion of and resubmission of the NDA during the third quarter of 2017.

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 $0.7 million during the year ended December 31, 2018 as compared to the prior year. This increase was primarily due to increases in legal expenses in connection with the Laboratories Majorelle SAS et al. v. Apricus Biosciences, Inc. et al., No. 1:17-cv-06625 (AT) (DCF) litigation, which was dismissed during the third quarter of 2018. This was partially offset by a $0.8 million decrease in bonus expense during the year ended December 31, 2018 as compared to the prior year.

Other Income and Expense

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

	Year Ended December 31,		2018 vs 2017	
	2018	2017	$ Change	% Change
Other (expense) income				
Interest expense, net	$ -	$ (83)	$ 83	-100%
Change in fair value of warrant liabilities	222	(646)	868	-134%
Loss on extinguishment of debt	-	(422)	422	-100%
Amendment of equity classified warrants	(293)	-	(293)	n/a
Other (expense) income, net	1	77	(76)	-99%
Total other (expense) income	$ (70)	$ (1,074)	$ 1,004	-93%

Interest Expense, Net

In October 2014, we entered into the Loan and Security Agreement (the "Credit Facility") with Oxford Finance LLC ("Oxford") and Silicon Valley Bank ("SVB") (Oxford and SVB are referred to together as the "Lenders"). On March 8, 2017, we repaid to the Lenders all amounts due and owed under the Credit Facility. The payment included the outstanding balance of the term loans in full, a prepayment fee of approximately 2%, a final payment equal to 6% of the original principal amount of each term loan and per diem interest for a total payment of $6.6 million.

Change in Fair Value of Warrant Liability

In connection with our February 2015 and January 2016 equity financings, we issued warrants to purchase up to 10,073 shares (the "February 2015 Warrants") and 18,939 shares, respectively, of our common stock at an exercise price of 546.00 and $264.00 per share, respectively. Pursuant to the January 2016 financing, the February 2015 Warrants were repriced from $546.00 to $264.00 per share.

The initial fair value of the 2015 and 2016 Warrants was determined using the Black-Scholes option pricing model on each respective transaction date and recorded as the initial carrying values of the common stock warrant liabilities. The fair value of the 2015 and 2016 Warrants was remeasured at each financial reporting period with any changes in fair value recognized as a change in fair value of warrant liability in the accompanying consolidated statements of operations (see notes 1 and 7 to our consolidated financial statements for further details).

In March 2018, we entered into the March 2018 Warrant Amendment with the holders of 2015 and 2016 Warrants which, among other things, (i) reduced the exercise price of the 2015 and 2016 Warrants from $264.00 to $21.30 per share, and (ii) changed certain provisions of the 2015 and 2016 Warrants such that the Warrants could no longer be net-cash settled. The fair value of the 2015 and 2016 Warrants on the date of the modification was $0.5 million, which resulted in a charge of $0.2 million to change in fair value of warrant liability on the consolidated statements of operations. Upon modification, the 2015 and 2016 Warrants were reclassified to stockholders' equity.

Amendment of Equity Classified Warrants

In September 2018, pursuant to the terms of the September 2018 SPA, outstanding warrants to purchase up to 89,239 shares of common stock previously issued to and held by the Purchaser were cancelled at the closing of the financing on September 24, 2018. The fair value of the portion of the September 2018 Warrants previously issued and outstanding was $0.6 million on the date of the modification, which resulted in a charge of $0.1 million to amendment of equity classified warrants on the consolidated statements of operations.

On June 22, 2018, the Company entered into the Subscription Agreement Amendment with the Investors, which, among other things, removed the Investors' preemptive rights with respect to future issuances of the Company's equity securities. Concurrently with the Subscription Agreement Amendment, the Company entered into the June 2018 Warrant Amendment with Sarissa Offshore regarding the 2015 and 2016 Warrants, pursuant to which the exercise price of the warrants was reduced from $21.30 to $12.60 per share. The amendment to the warrants resulted in a charge of approximately $17,000, which was recorded as amendment of equity classified warrants expense during the three months ended June 30, 2018.

In connection with the April 2018 Financing, we entered in the April 2018 Warrant Amendment, which (i) reduced the exercise price of the September 2017 Warrants and the September 2017 Placement Agent Warrants to $18.00 per share (the closing price of our stock on March 27, 2018, the date of the amendment), and (ii) changed the date upon which such warrants become exercisable to the effective date of the 2018 Charter Amendment. The April 2018 Warrant Amendment resulted in a charge of approximately $0.1 million, which was recorded as amendment of equity classified warrants in the consolidated statement of operations for the three months ended March 31, 2018.

Loss on Extinguishment of Debt

On March 8, 2017, pursuant to the Asset Purchase Agreement, (the "Ferring Asset Purchase Agreement") we entered into with Ferring International Center S.A. ("Ferring"), we repaid all outstanding amounts due and owed, including applicable termination fees, under the Loan and Security Agreement (the "Credit Facility") with Oxford Finance LLC, ("Oxford") and Silicon Valley Bank ("SVB"), and together with Oxford, the "Lenders"). The final payment included the outstanding balance of the term loans in full as well as (i) a prepayment fee contractually owed of approximately 2%, or $0.1 million, (ii) a final payment equal to 6% of the original principal amount of each term loan, or $0.6 million, and (iii) per diem interest of approximately $0.05 million, for a total payment of $6.6 million, which resulted in a loss on extinguishment of debt of $0.4 million.

Discontinued Operations

The operating results from our discontinued operations are as follows (in thousands):

	Year Ended December 31,	
	2018	**2017**
Product sales	$ -	$ 143
Royalty revenue	-	368
License fee revenue	-	-
Cost of goods sold	(24)	(74)
Cost of Sandoz rights	-	(10)
Operating expenses	-	(658)
Other expense	-	(16)
Gain on sale	-	12,317
(Loss) income from discontinued operations	$ (24)	$ 12,070

On March 8, 2017, we entered into the Ferring Asset Purchase Agreement, pursuant to which we sold to Ferring our assets and rights related to Vitaros outside of the United States for approximately $12.7 million, which consisted of an upfront payment of $11.5 million, $0.7 million for the delivery of certain product-related inventory (received in April 2017), and an aggregate of $0.5 million related to transition services, the payments of which were received in July 2017 and September 2017. We used approximately $6.6 million of the proceeds from the sale to repay all outstanding amounts due and owed, including applicable termination fees, under the Credit Facility with the Lenders.

As a result of the Ferring Asset Purchase Agreement, all product sales revenue, royalty revenue, license fee revenue and cost of goods sold have been reflected as discontinued operations in the consolidated statement of operations for both periods presented. Cost of Sandoz rights represents the payments owed by us to Sandoz as a condition under the termination agreement between the two parties related to Vitaros outside of the United States. In addition, operating expenses, such as the transaction costs directly related to the Ferring Asset Purchase Agreement, have been presented as discontinued operations.

Liquidity, Capital Resources and Financial Condition

We have experienced net losses and negative cash flows from operations each year since our inception. We recorded a net loss of approximately $9.2 million for the year ended December 31, 2018, we had an accumulated deficit of approximately $325.2 million as of December 31, 2018. Our cash balance was approximately $3.6 million as of December 31, 2018. Our history and other factors raise substantial doubt about our ability to continue as a going concern. We have principally been financed through the sale of our common stock and other equity securities, debt financings and up-front payments received from commercial partners for our products under development.

On September 20, 2018, we entered into a Securities Purchase Agreement (the "September 2018 SPA") with an accredited investor (the "Purchaser") for net proceeds of approximately $1.1 million. Pursuant to the September 2018 SPA, we sold 153.333 shares of our common stock, at a purchase price of $8.10 per share and warrants to purchase up to 115,000 shares of common stock, exercisable six months after issuance at an exercise price equal to $9.00 per share, in a private placement. In addition, we issued warrants to purchase up to 7,667 shares of common stock to H.C. Wainwright (the "September 2018 Placement Agent Warrants"). The September 2018 Placement Agent Warrants are exercisable six months after issuance at an exercise price of $10.125 per share, and expire five years from the initial exercise date. We also issued additional warrants to the Purchaser in an amount of 89,239 shares of common stock, exercisable six months after issuance at an exercise price equal to $12.00 per share (all warrants issued to the Purchaser in the September 2018 SPA, the "September 2018 Warrants"). The September 2018 Warrants are exercisable for five years from the initial exercise date. In addition, pursuant to the terms of the September 2018 SPA, outstanding warrants to purchase up to 89,239 shares of common stock previously issued to and held by the Purchaser were canceled at the closing, which occurred on September 24, 2018. It is explicitly stated in the Form of Warrant for both the September 2018 Warrants and the September 2018 Placement Agent Warrants that under no circumstances would we be required to net cash settle the warrants. In connection with the September 2018 SPA, the Purchaser agreed to enter into a voting agreement with us to vote all of their respective shares of our common capital stock in favor of the adoption of the Merger Agreement.

On June 22, 2018, we entered into a subscription agreement amendment (the "Subscription Agreement Amendment") with Sarissa Capital Domestic Fund LP ("Sarissa Domestic") and Sarissa Capital Offshore Master Fund LP ("Sarissa Offshore" together with Sarissa Domestic, the "Investors"), which, among other things, removed the Investors' preemptive rights with respect to future issuances of our equity securities. Concurrently with the Subscription Agreement Amendment, we entered into a warrant amendment (the "June 2018 Warrant Amendment") with Sarissa Offshore regarding the warrants to purchase common stock of the Company, issued in February 2015 (the "February 2015 Warrants") and January 2016 (together with the February 2015 Warrants, the "2015 and 2016 Warrants"), pursuant to which the exercise price of the warrants was reduced from $21.30 to $12.60 per share. Previously, in March 2018, we entered into a warrant amendment (the "March 2018 Warrant Amendment") with the holders of the 2015 and 2016 Warrants, which, among other things, (i) reduced the exercise price of the 2015 and 2016 Warrants from $264.00 to $21.30 per share, and (ii) amended certain provisions of the 2015 and 2016 Warrants such that they, effective as of the March 2018 Warrant Amendment, can no longer be net-cash settled.

On April 2, 2018, we completed a public offering (the "April 2018 Financing") for net proceeds of approximately $2.9 million, after deducting placement agent fees and other estimated offering expenses. Pursuant to the agreement, we sold 236,667 units (the "2018 Units") at a purchase price of $15.00 per share, with each unit consisting of one share of our common stock and one warrant to purchase 0.5 of a share of our common stock (the "April 2018 Warrants"). The April 2018 Warrants have an exercise price equal to $15.00 per share of common stock and were exercisable following our May 17, 2018 announcement that we had received stockholder approval of an amendment to our Amended and Restated Articles of Incorporation to increase the number of authorized shares of common stock to a total of 60,000,000 shares (the "2018 Charter Amendment") and the 2018 Charter Amendment became effective. The April 2018 Warrants will expire five years from that date. In addition, we issued warrants to purchase up to 11,833 shares of common stock (the "April 2018 Placement Agent Warrants") to H.C. Wainwright & Co., LLC ("H.C. Wainwright"). The April 2018 Placement Agent Warrants were exercisable upon the announcement of the effectiveness of the 2018 Charter Amendment at an exercise price of $18.75 per share, and also expire five years from that date.

On September 10, 2017, we entered into a Securities Purchase Agreement with certain accredited investors for net proceeds of approximately $3.1 million, after deducting commissions and estimated offering expenses. Pursuant to the agreement, we sold 71,220 shares of our common stock at a purchase price of $51.90 per share, and warrants to purchase up to 35,610 shares of common stock in a private placement (the "September 2017 Warrants"). The September 2017 Warrants were exercisable upon closing, or on September 13, 2017, at an exercise price equal to $50.10 per share of common stock and are exercisable for two and one half years from that date. In addition, we issued warrants to purchase up to 3,561 shares of common stock to H.C. Wainwright (the "September 2017 Placement Agent Warrants"). The September 2017 Placement Agent Warrants were originally exercisable upon closing at an exercise price of $64.80 per share, and also expire two and one half years from the closing date. In connection with the April 2018 Financing, the September 2017 Warrants and the September 2017 Placement Agent Warrants were amended to, among other things, (i) reduced the exercise price of the September 2017 Warrants and the September 2017 Placement Agent Warrants to $18.00 per share (the closing price of our stock on March 27, 2018, the date of the amendment), and (ii) changed the date upon which such warrants became exercisable to the effective date of the 2018 Charter Amendment, or May 17, 2018 (the "April 2018 Warrant Amendment").

On April 26, 2017, we completed an underwritten public offering (the "April 2017 Financing") for net proceeds of approximately $5.9 million, after deducting the underwriting discounts and commissions and our offering expenses. Pursuant to the underwriting agreement with H.C. Wainwright, we sold to H.C. Wainwright an aggregate of 167,667 units. Each unit consisted of one share of common stock and one warrant to purchase 0.75 of a share of common stock (the "April 2017 Warrants"), sold at a public offering price of $42.00 per unit. At the time of the offering closing, we did not currently have a sufficient number of authorized common stock to cover shares of common stock issuable upon the exercise of the warrants. The sufficient number of authorized common stock became available on May 17, 2017 when we received stockholder approval of the proposed amendment to our Amended and Restated Articles of Incorporation to increase the number of authorized shares of common stock (the "2017 Charter Amendment") and the 2017 Charter Amendment became effective. The April 2017 Warrants will expire five years from the date the warrants were exercisable, or May 17, 2017, and the exercise price of the April 2017 Warrants is $46.50 per share of common stock. In connection with this transaction, we issued to H.C. Wainwright warrants to purchase up to 8,383 shares of common stock (the "2017 Underwriter Warrants"). The 2017 Underwriter Warrants have substantially the same terms as the April 2017 Warrants, except that the 2017 Underwriter Warrants have a term of five years from the effective date of the related prospectus, or April 20, 2017, and an exercise price of $52.50 per share. The common shares, warrants and warrant shares were issued and sold pursuant to an effective registration statement on Form S- 1, which was previously filed with the SEC and declared effective on April 20, 2017, and a related prospectus.

On April 20, 2017, we entered into a warrant amendment with the holders of our warrants to purchase common stock, issued in a previous financing in September 2016 (the "September 2016 Warrants"), which, among other things, (i) reduced the exercise price of the warrants to $46.50 per share (the exercise price of the April 2017 Warrants), and (ii) changed the date upon which such warrants become exercisable to the effective date of the 2017 Charter Amendment, or May 17, 2017.

On March 8, 2017, we entered into the Ferring Asset Purchase Agreement, pursuant to which we sold to Ferring our assets and rights related to 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. We used approximately $6.6 million of the proceeds from the sale to repay all outstanding amounts due and owed, including applicable termination fees, under the Credit Facility with the Lenders.

We currently have an effective shelf registration statement on Form S-3 filed with the SEC under which we may offer from time to time any combination of debt securities, common and preferred stock and warrants. As of February 26, 2018, we had approximately $95.2 million available under our Form S-3 shelf registration statement. However, under current SEC regulations, at any time during which 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 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 March 14, 2019, our public float was approximately $124.1 million based on 15.3 million shares of our common stock outstanding at a price of $8.1008 per share, which was the closing sale price of our common stock on January 15, 2019. While our public float was greater than $75.0 million as of March 14, 2019, there is no guarantee that this will continue to be the case, and if our public float were to fall below $75.0 million, we would be 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. 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.

The accompanying 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 secure a development partner for U.S. Vitaros in order to overcome deficiencies raised in the 2018 CRL, if we believe it's commercially reasonable to do so;
- our ability to maintain compliance with the listing requirements of Nasdaq;
- 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 made by Ferring under the Ferring Asset Purchase Agreement;
- litigation expenses;
- the emergence and effect of competing or complementary products;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our ability to retain our current employees and the need and ability to hire additional management and scientific and medical personnel;
- the terms and timing of any collaborative, licensing or other arrangements that we have or may establish;
- the trading price of our common stock; and
- our ability to increase the number of authorized shares outstanding to facilitate future financing events.

We 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 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 affect future development and business activities, 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, and failure to obtain additional financing will have a material, adverse impact on our operations and business plan. No assurances can be given that we will be able to obtain additional financings.

Cash Flow Summary

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

	2018	2017
Net cash provided by (used in) operations		
Net cash used in operating activities from continuing operations	$ (8,126)	$ (10,571)
Net cash provided by financing activities from continuing operations	5,377	2,501
Net cash (used in) provided by discontinued operations	(3)	12,314
Net (decrease) increase in cash	$ (2,752)	$ 4,244

Operating Activities from Continuing Operations

Cash used in operating activities of $8.1 million in 2018 was primarily due to net loss of $9.2 million, adjusted for non-cash items such as the warrant liability revaluation of $0.2 million and stock based compensation expense of $1.3 million. Changes in operating assets and liabilities also contributed to the cash used in operating activities, such as decreases in prepaid expenses and accounts payable due to the decrease in R&D activity in the current year.

Cash used in operating activities from continuing operations of $10.6 million in 2017 was primarily due to a net loss from continuing operations of $11.7 million net of adjustments to net loss for non-cash items such as stock-based compensation expense of $1.1 million, the warrant liability revaluation of $0.6 million and the loss on extinguishment of debt of $0.4 million upon repayment of the Credit Facility. Changes in operating assets and liabilities also contributed to the cash used in operating activities, such as decreases in accounts payable and accrued expenses in the current year.

Investing Activities from Continuing Operations

There was no cash provided by investing activities during the 2018 or 2017.

Financing Activities from Continuing Operations

Cash provided by financing activities from continuing operations of $5.4 million during 2018 was due to net proceeds of $4.2 million from the issuance of common stock and warrants in our April and September 2018 financings, as well as proceeds of $1.3 million from the exercise of warrants during the first quarter of 2018.

Cash provided by financing activities of $2.5 million during 2017 was primarily attributable to the $9.3 million in net proceeds that we received from the issuance of common stock and warrants in our April 2017 and September 2017 financings, offset by the repayment of our Credit Facility of $7.1 million as a closing condition of the Ferring Asset Purchase Agreement.

Discontinued Operations

Cash provided by discontinued operations of $12.3 million during 2017 was a result of the Ferring Asset Purchase Agreement in March 2017, pursuant to which we sold to Ferring our assets and rights related to 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.

Off-Balance Sheet Arrangements

As of December 31, 2018, 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:

Stock Based Compensation

Stock based compensation expense includes charges related to options and restricted stock unit 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).

We also issue performance-based shares which represent a right to receive a certain number of shares of common stock based on the achievement of corporate performance goals and continued employment during the vesting period. At each reporting period, we reassess the probability of the achievement of such corporate performance goals and adjusts expense as necessary.

Valuation of Warrant Liability

Our outstanding common stock warrants issued in connection with our February 2015 and January 2016 financings 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.

The warrants issued in connection with our September 2016 financing were reclassified from warrant liabilities to stockholders' equity as a result of an amendment to such warrants executed as part of the April 2017 Financing. The warrants issued in September 2016 were amended so that, under no circumstance or by any event outside of our control, can these awards be cash settled. As a result, such warrants are no longer accounted for as liabilities.

We have issued other warrants that have similar terms whereas under no circumstance may the shares be settled in cash. As such, these warrants are equity-classified. See note 7 for further details.

Income Taxes

We recognize deferred taxes under the asset and liability method of accounting for income taxes by which deferred income taxes are recognized for differences between the financial statement and tax bases of assets and liabilities at enacted statutory tax rates in effect for the years in which the differences are expected to reverse. The effect on deferred taxes of a change in tax rates is recognized in income in the period that includes the enactment date. In addition, valuation allowances are established, when necessary, to reduce deferred tax assets to the amounts expected to be realized.

In consideration of our accumulated losses and lack of historical ability to generate taxable income to utilize our deferred tax assets, we have determined it is not more likely than not we will be able to realize any benefit from our temporary differences and have recorded a full valuation allowance. If we become profitable in the future at levels which cause management to conclude that it is more likely than not that we will realize all or a portion of the net operating loss carry-forward, we would record the estimated net realized value of the deferred tax asset at that time and would then provide for income taxes at a rate equal to our combined federal and state effective rates, which would be approximately 26% under current tax laws. Subsequent revisions to the estimated net realizable value of the deferred tax asset could cause our provision for income taxes to vary significantly from period to period.

Our policy is to recognize interest and penalties related to income tax matters in income tax expense. As the unrecognized tax benefits relate to un-utilized deferred tax assets and because we have generated net operating losses and capital losses since inception for both federal and state income tax purposes, no tax liabilities, penalties or interest have been recognized for balance sheet or statement of operations purposes as of and for the periods ended December 31, 2018 and 2017.

Tax Cuts and Jobs Act

On December 22, 2017, President Trump signed into law the tax legislation commonly known as the Tax Cuts and Jobs Act, or the Act. The effects of the new federal legislation are recognized upon enactment, which is the date the president signs a bill into law. The Act includes numerous changes in existing tax law, including a permanent reduction in the federal corporate income tax rate from 35% to 21%. The rate reduction took effect on January 1, 2018. We have concluded that the Act will cause our deferred tax assets to be revalued. Deferred income taxes result from temporary differences between the tax basis of assets and liabilities and their reported amounts in the financial statements that will result in taxable or deductible amounts in future years. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in years in which those temporary differences are expected to be recovered or settled. As changes in tax laws or rates are enacted, deferred tax assets and liabilities are adjusted through income tax expense. Based on currently available information, we recorded a $0.01 million reduction in the fourth quarter of 2018 related to the revaluation of our deferred tax assets, which will not result in additional tax expense in the quarter as we maintain a full valuation allowance on our deferred tax assets.

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

Shareholders and Board of Directors
Seelos Therapeutics, Inc. (formerly Apricus Biosciences, Inc.)

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Seelos Therapeutics, Inc. (formerly Apricus Biosciences, Inc.) or the "Company" as of December 31, 2018 and 2017, the related consolidated statements of operations, changes in stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company and subsidiaries at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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.

Reverse Merger

As described in Note 1, subsequent to December 31, 2018, Apricus Biosciences, Inc. completed a reverse merger with Seelos Therapeutics, Inc. Upon completion of the merger, Apricus Biosciences, Inc. changed its name to Seelos Therapeutics, Inc.

/s/ BDO USA, LLP
We have served as the Company's auditor since 2015.
San Diego, California

March 28, 2019

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

	December 31,	
	2018	**2017**
Assets		
Current assets		
Cash	$ 3,579	$ 6,331
Prepaid expenses and other current assets	106	261
Total current assets	3,685	6,592
Property and equipment, net	38	79
Other long term assets	37	35
Noncurrent assets of discontinued operations	-	-
Total assets	$ 3,760	$ 6,706
Liabilities and stockholders' equity (deficit)		
Current liabilities		
Accounts payable	$ 235	$ 58
Accrued expenses	644	650
Accrued compensation	272	863
Deferred revenue	-	12
Current liabilities of discontinued operations	21	-
Total current liabilities	1,172	1,583
Warrant liabilities	-	694
Other long term liabilities	16	58
Total liabilities	1,188	2,335
Commitments and contingencies (note 11)		
Stockholders' equity (deficit)		
Preferred stock, $.001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of December 31, 2018 and 2017	-	-
Common stock, $.001 par value, 60,000,000 and 30,000,000 shares authorized, 941,553 and 507,241 issued and outstanding as of December 31, 2018 and 2017, respectively	28	15
Additional paid-in-capital	327,773	320,343
Accumulated deficit	(325,229)	(315,987)
Total stockholders' equity (deficit)	2,572	4,371
Total liabilities and stockholders' equity (deficit)	$ 3,760	$ 6,706

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

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

	Year Ended December 31,	
	2018	**2017**
Operating expense		
Research and development	$ 1,220	$ 3,463
General and administrative	7,928	7,210
Loss on disposal of assets	-	2
Total operating expense	9,148	10,675
Loss before other expense	(9,148)	(10,675)
Other income (expense)		
Interest expense, net	-	(83)
Change in fair value of warrant liabilities	222	(646)
Loss on extinguishment of debt	-	(422)
Amendment of equity classified warrants	(293)	-
Other income, net	1	77
Total other expense	(70)	(1,074)
Loss from continuing operations	(9,218)	(11,749)
(Loss) income from discontinued operations	(24)	12,070
Net (loss) income	$ (9,242)	$ 321
Total earnings (loss) per share		
Continuing operations	$ (12.11)	$ (29.64)
Discontinued operations	$ (0.03)	$ 30.45
Total earnings (loss) per share	$ (12.14)	$ 0.81
Weighted average common shares outstanding used for basic and diluted earnings (loss) per share	761	396

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,	
	2018	**2017**
Cash flows from operating activities:		
Net income (loss)	$ (9,242)	$ 321
Net income (loss) from discontinued operations	(24)	12,070
Net loss from continuing operations	(9,218)	(11,749)
Adjustments to reconcile net loss to net cash used in operating activities from continuing operations:		
Depreciation and amortization	41	117
Non-cash interest expense	-	56
Stock-based compensation expense	1,301	1,138
Warrant liabilities revaluation	(222)	646
Amendment of equity classified warrants	293	-
Loss on debt extinguishment	-	422
Other	-	2
Changes in operating assets and liabilities from continuing operations:		
Prepaid expenses and other current assets	155	(84)
Other assets	(2)	25
Accounts payable	177	(705)
Accrued expenses	(6)	(681)
Accrued compensation	(591)	249
Deferred revenue	(12)	-
Other liabilities	(42)	(7)
Net cash used in operating activities from continuing operations	(8,126)	(10,571)
Cash flows from financing activities from continuing operations:		
Issuance of common stock and warrants	4,792	10,733
Issuance costs related to common stock and warrants	(690)	(1,392)
Proceeds from exercise of warrants	1,275	289
Repayment of notes payable	-	(7,129)
Net cash provided by financing activities from continuing operations	5,377	2,501
Cash flows from discontinued operations:		
Net cash (used in) provided by operating activities of discontinued operations	(3)	105
Net cash provided by investing activities of discontinued operations	-	12,209
Net cash (used in) provided by discontinued operations	(3)	12,314
Net (decrease) increase in cash	(2,752)	4,244
Cash, beginning of period	6,331	2,087
Cash, end of period	$ 3,579	$ 6,331
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ -	$ 92
Cash paid for income taxes	$ -	$ -
Non-cash investing and financing activities:		
Reclassification of warrant liabilities to equity	$ 472	$ 798
Issuance of placement agent warrants	$ 159	$ 287

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) Equity
Balance as of December 31, 2016	258	$ 8	$ 308,784	$ (316,308)	$ (7,516)
Stock-based compensation expense	-	-	1,138	-	1,138
Issuance of common stock and warrants	245	7	10,726	-	10,733
Issuance of common stock due to the vesting of restricted stock units, net of shares withheld to cover taxes	4	-	-	-	-
Issuance costs related to common stock and warrants	-	-	(1,392)	-	(1,392)
Proceeds from exercise of warrants	-	-	289	-	289
Reclassification of warrant liabilities to equity	-	-	798	-	798
Net income	-	-	-	321	321
Balance as of December 31, 2017	507	15	320,343	(315,987)	4,371
Stock-based compensation expense	-	-	1,301	-	1,301
Issuance of common stock due to the vesting of restricted stock units, net of shares withheld to cover taxes	10	-	-	-	-
Issuance of common stock and warrants	390	12	4,780	-	4,792
Issuance costs related to common stock and warrants	-	-	(690)	-	(690)
Proceeds from exercise of warrants	35	1	1,274	-	1,275
Amendment of equity classified warrants	-	-	293	-	293
Reclassification of warrant liabilities to equity			472		472
Net loss	-	-	-	(9,242)	(9,242)
Balance as of December 31, 2018	942	$ 28	$ 327,773	$ (325,229)	$ 2,572

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

On January 24, 2019, the Company completed a reverse merger transaction (the "Merger") with Seelos Therapeutics, Inc., a Delaware corporation (now known as Seelos Corporation) ("STI"). Upon completion of the Merger, the Company changed its name to Seelos Therapeutics, Inc. and will focus on the development and commercialization of CNS therapeutics with known mechanisms of action in areas with a highly unmet medical need. On January 23, 2019, in connection with, and prior to the completion of, the Merger, the Company effected a reverse stock split of our common stock at a ratio of 1-for-30 (the "Reverse Stock Split"). Unless otherwise noted, references to share amounts, and other information have been adjusted to reflect the Reverse Stock Split. Shares of the Company's common stock commenced trading on the Nasdaq Capital Market under the ticker symbol "SEEL" as of market open on January 24, 2019. The Company's previous ticker symbol was "APRI". See note 2 below for more information regarding the Merger.

These financial statements are of Apricus Biosciences, Inc. prior to the Merger because the Merger was consummated after the period covered by these financial statements. Accordingly, the historical financial information included in this Annual Report on Form 10-K, unless otherwise indicated or as the context otherwise requires, is that of Apricus Biosciences Inc. prior to the Merger.

The Company plans on developing its clinical and regulatory strategy with its internal research and development team with a view toward prioritizing market introduction as quickly as possible. The Company's lead programs following the completion of the merger are SLS-002 for the potential treatment of suicidality in post-traumatic stress disorder, and in major depressive disorder, SLS-005 for Sanfilippo syndrome and SLS-006 for the potential treatment of Parkinson's disease.

Additionally, the Company is developing several preclinical programs, most of which have well-defined mechanisms of action, including: 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.

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 generally accepted accounting principles ("GAAP") requires the Company to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. The Company's most significant estimates relate to the valuation of stock-based compensation, the valuation of its warrant liabilities, the impairment of long-lived assets and valuation allowances for the Company's deferred tax assets. The Company's actual results may differ from these estimates under different assumptions or conditions.

Liquidity

The accompanying consolidated financial statements have been prepared on a basis which assumes the Company is a going concern and that contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company had an accumulated deficit of approximately $325.2 million as of December 31, 2018. As of December 31, 2018, the Company had a cash balance of approximately $3.6 million. The Company also reported negative cash flows from operations of $8.1 million for the year ended December 31, 2018. The Company's history and other factors raise substantial doubt about the Company's ability to continue as a going concern. The Company has principally been financed through the sale of its common stock and other equity securities, debt financings, up-front payments received from commercial partners for the Company's products under development, and through the sale of assets.

On September 20, 2018, the Company entered into a Securities Purchase Agreement (the "September 2018 SPA") with an accredited investor (the "Purchaser") for net proceeds of approximately $1.1 million. Pursuant to the September 2018 SPA, the Company sold 153,333 shares of the Company's common stock, at a purchase price of $8.10 per share and warrants to purchase up to 115,000 shares of common stock, exercisable six months after issuance at an exercise price equal to $9.00 per share, in a private placement. In addition, the Company issued warrants to purchase up to 7,667 shares of common stock to H.C. Wainwright (the "September 2018 Placement Agent Warrants"). The September 2018 Placement Agent Warrants are exercisable six months after issuance at an exercise price of $10.125 per share, and expire five years from the initial exercise date. The Company also issued additional warrants to the Purchaser in an amount of 89,239 shares of common stock, exercisable six months after issuance at an exercise price equal to $12.00 per share (all warrants issued to the Purchaser in the September 2018 SPA, the "September 2018 Warrants"). The September 2018 Warrants are exercisable for five years from the initial exercise date. In addition, pursuant to the terms of the September 2018 SPA, outstanding warrants to purchase up to 89,239 shares of common stock previously issued to and held by the Purchaser were canceled at the closing, which occurred on September 24, 2018. It is explicitly stated in the Form of Warrant for both the September 2018 Warrants and the September 2018 Placement Agent Warrants that under no circumstances would the Company be required to net cash settle the warrants. In connection with the September 2018 SPA, the Purchaser agreed to enter into a voting agreement with the Company to vote all of their respective shares of the Company's capital stock in favor of the adoption of the Merger Agreement.

On June 22, 2018, the Company entered into a subscription agreement amendment (the "Subscription Agreement Amendment") with Sarissa Capital Domestic Fund LP ("Sarissa Domestic") and Sarissa Capital Offshore Master Fund LP ("Sarissa Offshore" and together with Sarissa Domestic, the "Investors"), which, among other things, removed the Investors' preemptive rights with respect to future issuances of the Company's equity securities. Concurrently with the Subscription Agreement Amendment, the Company entered into a warrant amendment (the "June 2018 Warrant Amendment") with Sarissa Offshore regarding the warrants to purchase common stock of the Company, issued in February 2015 (the "February 2015 Warrants") and January 2016 (together with the February 2015 Warrants, the "2015 and 2016 Warrants"), pursuant to which the exercise price of the warrants was reduced from $21.30 to $12.60 per share. Previously, in March 2018, the Company entered into a warrant amendment (the "March 2018 Warrant Amendment") with the holders of the 2015 and 2016 Warrants, which, among other things, (i) reduced the exercise price of the 2015 and 2016 Warrants from $264.00 to $21.3 per share, and (ii) amended certain provisions of the 2015 and 2016 Warrants such that they, effective as of the March 2018 Warrant Amendment, can no longer be net-cash settled.

On April 2, 2018, the Company completed a public offering (the "April 2018 Financing") for net proceeds of approximately $3.1 million, after deducting placement agent fees and other estimated offering expenses. Pursuant to the agreement, the Company sold 236,667 units (the "2018 Units") at a purchase price of $15.00 per share, with each unit consisting of one share of the Company's common stock and one warrant to purchase 0.5 of a share of the Company's common stock (the "April 2018 Warrants"). The April 2018 Warrants have an exercise price equal to $15.00 per share of common stock and were exercisable following the Company's May 17, 2018 announcement that it had received stockholder approval of an amendment to its Amended and Restated Articles of Incorporation to increase the number of authorized shares of common stock to a total of 60,000,000 shares (the "2018 Charter Amendment") and the 2018 Charter Amendment became effective. The April 2018 Warrants will expire five years from that date. In addition, the Company issued warrants to purchase up to 11,833 shares of common stock (the "April 2018 Placement Agent Warrants") to H.C. Wainwright & Co., LLC ("H.C. Wainwright"). The April 2018 Placement Agent Warrants were exercisable upon the announcement of the effectiveness of the 2018 Charter Amendment at an exercise price of $18.75 per share, and also expire five years from that date.

On September 10, 2017, the Company entered into a Securities Purchase Agreement (the "September 2017 SPA") with certain investors for net proceeds of approximately $3.1 million, after deducting commissions and estimated offering expenses payable by the Company. Pursuant to the agreement, the Company sold 71,220 shares of the Company's common stock at a purchase price of $51.90 per share, and warrants to purchase up to 35,610 shares of common stock in a private placement (the "September 2017 Warrants"). The September 2017 Warrants were originally exercisable upon closing, or on September 13, 2017, at an exercise price equal to $50.10 per share of common stock and are exercisable for two and one half years from that date. In addition, the Company issued warrants to purchase up to 3,561 shares of common stock to H.C. Wainwright (the "September 2017 Placement Agent Warrants"). The September 2017 Placement Agent Warrants were originally exercisable upon closing at an exercise price of $64.80 per share, and also expire two and one half years from the closing date. In connection with the April 2018 Financing, the September 2017 Warrants and the September 2017 Placement Agent Warrants were amended to, among other things, (i) reduce the exercise price of the warrants to $18.00 per share (the closing price of the Company's stock on March 27, 2018, or the date of the amendment), and (ii) change the date upon which such warrants became exercisable to the effective date of the 2018 Charter Amendment, or May 17, 2018 (the "April 2018 Warrant Amendment").

On April 26, 2017, the Company completed an underwritten public offering (the "April 2017 Financing") for net proceeds of approximately $5.9 million, after deducting the underwriting discounts and commissions and offering expenses payable by the Company. Pursuant to the underwriting agreement with H.C. Wainwright, the Company sold to H.C. Wainwright an aggregate of 167,667 units (the "2017 Units"). Each unit consisted of one share of common stock and one warrant to purchase 0.75 of a share of common stock (the "April 2017 Warrants"), sold at a public offering price of $42.00 per unit. At the time of the offering closing, the Company did not have a sufficient number of authorized common stock to cover shares of common stock issuable upon the exercise of the April 2017 Warrants. The sufficient number of authorized common stock became available on May 17, 2017 when the Company received stockholder approval of the proposed amendment to the Company's Amended and Restated Articles of Incorporation to increase the number of authorized shares of common stock (the "2017 Charter Amendment") and the 2017 Charter Amendment became effective on that date. The April 2017 Warrants will expire five years from May 17, 2017, the date they became exercisable, and the exercise price of the April 2017 Warrants is $46.50 per share of common stock. In connection with this transaction, the Company issued to H.C. Wainwright warrants to purchase up to 8,383 shares of common stock (the "2017 Underwriter Warrants"). The 2017 Underwriter Warrants have substantially the same terms as the April 2017 Warrants sold concurrently to the investors in the offering, except that the 2017 Underwriter Warrants have a term of five years from the effective date of the related prospectus, or April 20, 2017, and an exercise price of $52.50 per share. The common shares, warrants and warrant shares were issued and sold pursuant to an effective registration statement on Form S-1, which was previously filed with the SEC and declared effective on April 20, 2017, and a related prospectus.

On April 20, 2017, the Company entered into a warrant amendment (the "April 2017 Warrant Amendment") with the holders of the Company's September 2016 Warrants (as defined below) issued in a financing in September 2016, (the "September 2016 Financing"), which, among other things, (i) reduced the exercise price of the September 2016 Warrants to $46.50 per share (the exercise price of the April 2017 Warrants), and (ii) changed the date upon which the September 2016 Warrants became exercisable to the effective date of the 2017 Charter Amendment, or May 17, 2017.

On March 8, 2017, the Company entered into an asset purchase agreement (the "Ferring Asset Purchase Agreement") with Ferring International Center S.A. ("Ferring'), pursuant to which it sold to Ferring its assets and rights related to 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. The Company used approximately $6.6 million of the proceeds from the sale to repay all outstanding amounts due and owed, including applicable termination fees, under its Loan and Security Agreement (the "Credit Facility") with Oxford Finance LLC ("Oxford") and Silicon Valley Bank ("SVB" and together as the "Lenders").

The Company currently has an effective shelf registration statement on Form S-3 filed with the Securities and Exchange Commission ("SEC") under which it may offer from time to time any combination of debt securities, common and preferred stock and warrants. As of December 31, 2018, the Company had approximately $95.2 million available under its Form S-3 shelf registration statement. Under current SEC regulations, at any time during which the aggregate market value of the Company's common stock held by non-affiliates ("public float"), is less than $75.0 million, the amount it can raise through primary public offerings of securities in any twelve-month period using shelf registration statements is limited to an aggregate of one-third of the Company's public float. SEC regulations permit the Company to use the highest closing sales price of the Company's common stock (or the average of the last bid and last ask prices of the Company's common stock) on any day within 60 days of sales under the shelf registration statement. While the Company's public float was greater than $75.0 million as of March 14, 2019, there is no guarantee that this will continue to be the case, and if the Company's public float were to fall below $75.0 million, the Company would be limited to an aggregate of one-third of its public float in the amount it could raise through primary public offerings of securities in any twelve-month period using shelf registration statements. The Company still would 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 the Company's ability to conduct certain types of financing activities, or may affect the timing of and amounts it can raise by undertaking such activities.

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

- its ability to raise additional funds to finance its operations;
- its ability to maintain compliance with the listing requirements of The Nasdaq Capital Market ("Nasdaq");
- the outcome, costs and timing of clinical trial results for the Company's current or future product candidates;
- litigation expenses and the extent and amount of any indemnification claims;
- the emergence and effect of competing or complementary products;
- its ability to maintain, expand and defend the scope of its intellectual property portfolio, including the amount and timing of any payments the Company may be required to make, or that it may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- its ability to retain its 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 it has or may establish;
- the trading price of its common stock; and
- its ability to increase the number of authorized shares outstanding to facilitate future financing events.

The Company will likely need to raise substantial additional funds through one or more of the following: issuance of additional debt or equity, or the completion of a licensing transaction for one or more of the Company's pipeline assets. 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 debt financings will likely have a dilutive effect on the holdings of the Company's existing stockholders.

On April 10, 2018, the Company was notified that, based on the previous thirty consecutive business days, the Company's 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) (the "Bid Price Requirement") and at that time, the Company was provided 180 calendar days, or until October 8, 2018, to regain compliance.

On October 9, 2018, the Company received a letter from Nasdaq indicating that the Company's common stock has not regained compliance with the Bid Price Requirement. However, in accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has been provided an additional 180 calendar day period, or until April 8, 2019, to regain compliance. The Nasdaq Staff's determination that the Company is eligible for additional time is based on the Company meeting the continued listing requirement for market value of publicly held shares and all other applicable requirements for initial listing on the Nasdaq Capital Market, with the exception of the Bid Price Requirement, and the Company's written notice of its intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. If at any time before April 8, 2019, the closing bid price of the Company's common stock is at least $1.00 per share for a minimum of ten consecutive business days, the Nasdaq Staff will provide written confirmation of compliance with Rule 5550(a) and this matter will be closed. The Nasdaq letter has no immediate effect on the listing or trading of the Company's common stock and the common stock will continue to trade on The Nasdaq Capital Market under the symbol "APRI." The Company intends to monitor the bid price of its common stock and consider available options if its common stock does not trade at a level likely to result in the Company regaining compliance with the Bid Price Requirement by April 8, 2019. If compliance cannot be demonstrated by April 8, 2019, the Nasdaq Staff will provide written notification that the Company's common stock will be delisted. At that time, the Company may appeal the Nasdaq Staff's determination to a Hearings Panel.

On February 7, 2019, the Company was notified by the Nasdaq Staff that for more than the last 10 consecutive business days, from January 24, 2019 through February 6, 2019, the closing bid price of the Company's common stock had been at $1.00 per share or greater. Accordingly, the Company has regained compliance with Listing Rule 5550(a)(2), and this matter is now closed.

Warrant Liabilities

Prior to 2018, the Company's 2015 and 2016 Warrants were classified as liabilities in the accompanying consolidated 2017 balance sheet as they contained provisions that were considered outside of the Company's control, such as requiring the Company to maintain active registration of the shares underlying such warrants. The 2015 and 2016 Warrants were recorded at fair value using the Black-Scholes option pricing model. The fair value of these warrants was 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 for 2017.

In March 2018, the Company entered into the March 2018 Warrant Amendment with the holders of its 2015 and 2016 Warrants, which amended the terms so that in no circumstances may the 2015 and 2016 Warrants be net-cash settled. As a result, the fair value of the 2015 and 2016 Warrants at the date of the modification were reclassified to equity.

All of the Company's outstanding warrants, other than the Pre-Merger Warrants, have similar terms whereas under no circumstance may the warrants be net-cash settled. As such, all warrants are equity-classified. See note 7 for further details.

Fair Value of Financial Instruments

The Company's financial instruments consist principally of accounts payable, accrued expenses, and historically, its Credit Facility with the Lenders.

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.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets. The Company estimates useful lives as follows:

- Machinery and equipment: three to five years
- Furniture and fixtures: ten years
- Computer software: five years

Amortization of leasehold improvements and capital lease equipment is provided on a straight-line basis over the shorter of their estimated useful lives or the lease term. The costs of additions and betterments are capitalized, and repairs and maintenance costs are charged to operations in the periods incurred (see note 5 for further details).

Leases

Leases are reviewed and classified as capital or operating at their inception. 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. In January 2018, the Company subleased a portion of its office space. During the first quarter of 2018, the Company recorded a liability for the present value of the remaining lease due, offset by the sublease income reasonably expected over the remaining term of the lease.

Fair Value Measurements

The Company determines the fair value measurements of applicable assets and liabilities based on a three-tier fair value hierarchy established by accounting guidance and prioritizes the inputs used in measuring fair value. These tiers include: Level 1, defined as observable inputs such as quoted market prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions. The Company's common stock warrant liabilities were measured and disclosed at fair value on a recurring basis, and were classified within the Level 3 designation.

In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, the level in the fair value hierarchy within which the fair value measurement in its entirety falls has been determined based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability.

In March 2018, the Company entered into the March 2018 Warrant Amendment with the holders of its 2015 and 2016 Warrants, which amended the terms so that in no circumstances may the 2015 and 2016 Warrants be net-cash settled. As a result, the Company's 2015 and 2016 Warrants were reclassified from liabilities to equity during the first quarter of 2018 and will no longer be measured at fair value on a recurring basis.

The following table presents the Company's fair value hierarchy for its warrant liabilities measured at fair value on a recurring basis (in thousands) as of December 31, 2017:

Warrant liabilities	Quoted Market Prices for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Balance as of December 31, 2017	$ -	$ -	$ 694	$ 694

The common stock warrant liabilities were recorded at fair value using the Black-Scholes option pricing model. There were no liabilities classified as warrants as of December 31, 2018. The following assumptions were used in determining the fair value of the common stock warrant liabilities valued using the Black-Scholes option pricing model as of December 31, 2017:

	December 31, 2017
Risk-free interest rate	2.2%-2.2%
Volatility	89%-89.41%
Dividend yield	- %
Expected term	5.04-5.17
Weighted average fair value	$ 24.00

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, 2017	$ 694
Change in fair value measurement of warrant liability	(222)
Warrant liability reclassified to stockholders' equity	(472)
Balance as of December 31, 2018	$ -

Of the inputs used to value the outstanding common stock warrant liabilities as of December 31, 2018, the most subjective input is the Company's estimate of expected volatility of its common stock.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss is recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than it's carrying amount. If such assets are considered impaired, the amount of the impairment loss recognized is measured as the amount by which the carrying value of the asset exceeds the fair value of the asset, fair value being determined based upon future cash flows or appraised values, depending on the nature of the asset. The Company recognized no impairment losses during either of the periods presented within its financial statements.

Research and Development

Research and development costs are expensed as incurred and include the cost of 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 net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the same period. Diluted net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares and common equivalent shares outstanding during the same period. Common equivalent shares may be related to stock options, restricted stock units, or warrants. The Company excludes common stock equivalents from the calculation of diluted net income (loss) per share when the effect is anti-dilutive.

The following securities that could potentially decrease net income (loss) per share in the future are not included in the determination of diluted income (loss) per share as their effect is anti-dilutive (in thousands):

	Year Ended December 31,	
	2018	2017
Outstanding stock options	29	12
Outstanding warrants	437	236
Restricted stock units	9	24
	475	272

Stock-Based Compensation

The estimated grant date fair value of stock options granted to employees and directors is calculated based upon the closing stock price of the Company's 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. The Company estimates the fair value of each option award on the date of grant using the Black-Scholes option pricing model. The value of restricted stock unit grants is calculated based upon the closing stock price of the Company's common stock on the date of the grant.

Segment Information

The Company operates under one segment which develops pharmaceutical products.

Geographic Information

Revenues (included in discontinued operations) by geographic area for the Company's operations are as follows (in thousands):

	Year Ended December 31,	
	2018	2017
Europe (1)(2)	$ -	$ 364
Canada(1)	-	142
Other(1)(2)	-	5
	$ -	$ 511

(1) As a result of the Ferring Asset Purchase Agreement, all revenues have been reflected as discontinued operations in the statement of operations for all periods presented.
(2) Amounts included have not been broken out by country as it is impractical to do so given the nature and structure of the license agreements which cover multiple countries and/or territories. The basis for attributing product sales and royalty revenues from external customers to individual countries was based on the geographic location of the end user customer.

All of the Company's net long-lived assets were located in the United States for each of the years ended December 31, 2018 and 2017, respectively.

Recent Accounting Pronouncements

In May 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. ASU 2016-12, *Revenue from Contracts with Customers*, the amendment of which addressed narrow-scope improvements to the guidance on collectability, noncash consideration, and completed contracts at transition as well as providing a practical expedient for contract modifications. In April 2016 and March 2016, the FASB issued ASU No. 2016-10 and ASU No. 2016-08, respectively, the amendments of which further clarified aspects of Topic 606: identifying performance obligations and the

licensing and implementation guidance and intended to improve the operability and understandability of the implementation guidance on principal versus agent considerations. The FASB issued the initial release of Topic 606 in ASU No. 2014-09, which requires entities to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Entities may use a full retrospective approach or report the cumulative effect as of the date of adoption. In July 2015, the FASB issued ASU No. 2015-14, which deferred the effective date of ASU 2014-09 by one year to annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, for public entities, though early adoption was permitted. The Company adopted the standard on January 1, 2018 using a modified retrospective approach with the cumulative effect of adopting the standard recognized at the date of initial application being zero. Due to the Company's sale of certain assets and rights to Ferring in March 2017 (see note 2), the Company does not currently have a revenue stream. Accordingly, the adoption of this update on January 1, 2018 does not have a material effect on its consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU 2016-2, *Leases*. 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 is currently evaluating whether the adoption of the new standard will have a material effect on its consolidated financial statements and related disclosures.

2. MERGER

On January 24, 2019, the Company completed its business combination with STI in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of July 30, 2018 (the "Merger Agreement"), by and among the Company, Arch Merger Sub, Inc. ("Merger Sub"), and STI, as amended by Amendment No. 1 thereto made and entered into as of October 16, 2018 (the "First Amendment"), Amendment No. 2 thereto made and entered into as of December 14, 2018 (the "Second Amendment") and Amendment No. 3 thereto made and entered into as of January 16, 2019 (the "Third Amendment" and the Merger Agreement, as amended by the First Amendment, Second Amendment and Third Amendment, the "Amended Merger Agreement"), pursuant to which Merger Sub merged with and into STI, with STI surviving as the Company's wholly-owned subsidiary. On January 23, 2019, in connection with, and prior to the completion of, the Merger, the Company effected a reverse stock split of its common stock, par value $0.001 per share, at a ratio of 1-for-30 (the "Reverse Stock Split"), and on January 24, 2019, immediately after completion of the Merger, the Company changed its name to "Seelos Therapeutics, Inc." Following the completion of the Merger, the business conducted by the Company became primarily the business conducted by STI, which is a clinical-stage biopharmaceutical company focused on the development and advancement of novel therapeutics to address unmet medical needs for the benefit of patients with central nervous system disorders.

Under the terms of the Amended Merger Agreement, the Company issued shares of its common stock to the stockholders of STI at an exchange rate of 0.7704 shares of its common stock, after taking into account the Reverse Stock Split, for each share of STI's common stock outstanding immediately prior to the Merger. The exchange rate was determined through arms'-length negotiations between the Company and the STI. The Company also assumed all of the stock options outstanding under STI's 2016 Equity Incentive Plan (the "2016 Plan") with such stock options henceforth representing the right to purchase a number of shares of the Company's common stock equal to 0.7704 multiplied by the number of shares of STI's common stock previously represented by such options.

Immediately after the Merger, there were approximately 6,221,822 shares of the Company's common stock outstanding, subject to rounding up any fractional shares as a result of the Reverse Stock Split as further described below. Immediately after the Merger, the former stockholders, optionholders and noteholders of STI owned, or held rights to acquire, approximately 84.85% of the fully-diluted shares of the Company's common stock, which for these purposes is defined as the outstanding shares of common stock, plus restricted stock units and "in the money" options and warrants to purchase shares of Common Stock,

assuming that all of its "in the money" options and warrants outstanding immediately prior to the Merger were exercised on a cashless basis immediately prior to the closing of the Merger (the "Fully-Diluted Capitalization"), with its stockholders, optionholders, restricted stock unit holders and warrantholders immediately prior to the Merger owning, or holding rights to acquire, approximately 15.15% of the Fully-Diluted Capitalization.

The shares of common stock issued to the former stockholders of STI were registered with the SEC.

The shares of the Company's common stock listed on the Nasdaq Capital Market, previously trading through the close of business on January 23, 2019 under the ticker symbol "APRI," commenced trading on the Nasdaq Capital Market, on a post-Reverse Stock Split adjusted basis, under the ticker symbol "SEEL" on January 24, 2019.

Contingent Value Rights Agreement

Upon the closing of the Merger, the Company, STI, Richard Pascoe, as representative of the Company's stockholders, and a rights agent entered into the Contingent Value Rights Agreement (the "CVR Agreement"). Pursuant to the CVR Agreement, Company stockholders will receive one CVR for each share of the Company's common stock held of record immediately prior to the closing of the Merger. Each CVR will represent the right to receive payments based on the Company's Vitaros assets. 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 the Vitaros assets, including any contingent payments, less reasonable transaction expenses. The Company is entitled to retain the first $500,000 and 10% of any contingent payments. In order to be eligible for the CVR, a Company stockholder must have been a holder of record at the close of business immediately prior to the closing of the Merger. The Company agreed to use commercially reasonable efforts to out-license or sell the Vitaros assets for a period of three years following the closing of the Merger.

The CVRs are not be transferable, except in limited circumstances and will not be registered with the SEC. Richard Pascoe, the Company's former President and CEO, was appointed to serve as the representative of the CVR holders' interests under the CVR Agreement.

3. FERRING ASSET PURCHASE AGREEMENT AND DISCONTINUED OPERATIONS

On March 8, 2017, the Company entered into the Ferring Asset Purchase Agreement, pursuant to which, and on the terms and subject to the conditions thereof, among other things, the Company agreed to sell to Ferring its assets and rights (the "Purchased Assets") related to the business of developing, marketing, distributing, and commercializing, outside the United States, the Company's products currently marketed or in development, intended for the topical treatment of sexual dysfunction (the "Product Business"), including products sold under the name Vitaros (the "Products") for approximately $12.7 million. The Purchased Assets include, among other things, certain pending and registered patents and trademarks, contracts, manufacturing equipment and regulatory approvals relating to the Products outside of the United States. The Company retained the U.S. development and commercialization rights for Vitaros and a license from Ferring (the "Ferring License") for intellectual property rights for Vitaros and other products which relate to development both within the United States and internationally.

Pursuant to the terms of the Ferring Asset Purchase Agreement, Ferring paid the Company $11.5 million in cash at closing and paid approximately $0.7 million for the value of inventory related to the Products in April 2017. The Company was also eligible to receive two additional quarterly payments totaling $0.5 million for transition services, the first of which was received in July 2017 and the second of which was received in September 2017. The Company used a portion of the proceeds from the sale of the Purchased Assets to repay all amounts owed, including applicable termination fees, under the Credit Facility, which was approximately $6.6 million. The extinguishment of the Credit Facility was a stipulation of the Ferring Asset Purchase Agreement; however, since it was corporate debt, the loss on extinguishment was not offset against the gain on the sale of the Purchased Assets.

As of the transaction date, Ferring assumed responsibility for future obligations under the purchased contracts and regulatory approvals, as well as other liabilities associated with the Purchased Assets arising after the closing date, including $1.1 million, the remainder of the installment payments owed by the Company to Sandoz as a condition under the termination agreement between the two parties. The Company retained all liabilities associated with the Purchased Assets arising prior to the closing date.

Under the Ferring Asset Purchase Agreement, the Company has also agreed to indemnify Ferring for, among other things, breaches of its representations, warranties and covenants, any liability for which it remains responsible and its failure to pay certain taxes or comply with certain laws, subject to a specified deductible in certain cases. The Company's aggregate liability under such indemnification claims is generally limited to $2.0 million.

At the closing of the Ferring Asset Purchase Agreement, the Company entered into the Ferring License with respect to certain intellectual property rights necessary to or useful for its exploitation of the Purchased Assets within the United States and for its exploitation of the Purchased Assets in certain fields outside of sexual dysfunction, including for the treatment of Raynaud's Phenomenon, outside the United States. The parties granted one another a royalty free, perpetual and non-exclusive license to product know-how in their respective fields and territories and Ferring granted the Company a royalty-free, perpetual and exclusive license to certain patents in the field of sexual dysfunction in the United States and in certain fields other than sexual dysfunction outside of the United States.

The Ferring Asset Purchase Agreement was treated as a sale of a business and the total proceeds from the sale were allocated to the Purchased Assets. The total gain on sale of the Purchased Assets to Ferring consisted of the following:

Upfront payment received	$ 11,500
Transition services payments	500
Payment received for inventory	709
Total proceeds from sale	$ 12,709
Carrying value of assets sold in sale	(1,578)
Liabilities transferred upon sale	1,186
Total gain on sale of Purchased Assets	$ 12,317

Discontinued Operations

The Company had $0.02 million in accrued expenses related to discontinued operations as of December 31, 2018. There were no assets and liabilities presented as discontinued operations as of December 31, 2017.

The operating results of the Company's discontinued operations are as follows (in thousands):

	Year Ended December 31,	
	2018	**2017**
Product sales	$ -	$ 143
Royalty revenue	-	368
License fee revenue	-	-
Cost of goods sold	(24)	(74)
Cost of Sandoz rights	-	(10)
Operating expenses	-	(658)
Other expense	-	(16)
Gain on sale	-	12,317
(Loss) income from discontinued operations	$ (24)	$ 12,070

Product sales, royalty revenue and cost of goods sold all relate to the sale of Vitaros product outside of the United States. Historically, the Company relied on its former commercial partners to sell Vitaros in approved markets and received royalty revenue from its former commercial partners based upon the amount of those sales. Royalty revenues were computed and recognized on a quarterly basis, typically one quarter in arrears, and at the contractual royalty rate pursuant to the terms of each respective license agreement. The Company recorded $0.4 million in royalty revenue during the year ended December 31, 2017 related to sales of Vitaros prior to the completion of the Ferring Asset Purchase Agreement, during the fourth quarter of 2016 and the first quarter of 2017. "Cost of Sandoz rights" represents the payments owed by the Company to Sandoz as a condition under the termination agreement between the two parties related to Vitaros outside of the United States. Operating expenses for the current periods include primarily patent and legal fees and accounting expenses incurred in connection with the Ferring Asset Purchase Agreement.

4. ALLERGAN IN-LICENSING AGREEMENT

In 2009, Warner Chilcott Company, Inc., now a subsidiary of Allergan, acquired the commercial rights to Vitaros in the United States. In September 2015, the Company entered into a license agreement and amendment to the original agreement with Warner Chilcott Company, Inc., granting the Company exclusive rights to develop and commercialize Vitaros in the United States in exchange for a $1.0 million upfront payment, paid in September 2015, and a $1.5 million regulatory milestone payment, paid in September 2017 following the FDA's acknowledgment of receipt of the Company's NDA resubmission. Since the intangibles acquired in the license agreement do not have alternative future use, all costs incurred including the upfront payment and the regulatory milestone payment, were treated as research and development expense.

As part of the license agreement, Allergan has the right to exercise a one-time opt-in right to assume all future commercialization activities in the United States, assuming FDA approval, in exchange for a total of $25.0 million in upfront and potential launch milestone payments owed to the Company for that right, plus a high double-digit royalty in the ten to twenty percent range on Allergan's net sales of the product. If Allergan elects not to exercise its opt-in right, the Company may commercialize Vitaros, and in return, pay Allergan a high double-digit royalty in the ten to twenty percent range on our net sales of the product.

In 2008, the FDA issued a complete response letter (the "2008 CRL") for the Vitaros NDA, identifying certain deficiencies in the application. Based on the Company's 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 and new non-clinical studies, the Company resubmitted the Vitaros NDA in August 2017.

On February 15, 2018, the FDA issued a CRL indicating that the modest treatment effect did not outweigh certain safety concerns specific to the 2.5% concentration of its permeation enhancer NexACT (DDAIP.HCl) contained in the current formulation and identifying deficiencies related to chemistry, manufacturing and controls.

In April 2018, the Company met with the FDA and confirmed that two new Phase 3 clinical efficacy trials would be necessary at a lower formulation concentration in order to potentially reach approval.

5. OTHER FINANCIAL INFORMATION

Property and Equipment

Property and equipment are comprised of the following (in thousands):

	December 31,	
	2018	**2017**
Leasehold improvements	$ 20	$ 20
Machinery and equipment	270	270
Capital lease equipment	76	76
Computer software	130	130
Furniture and fixtures	25	25
Total property and equipment	521	521
Less: accumulated depreciation and amortization	(483)	(442)
Property and equipment, net	$ 38	$ 79

Depreciation expense totaled $0.04 million and $0.1 million for the years ended December 31, 2018 and 2017, respectively.

Accrued Expenses

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

	December 31,	
	2018	2017
Professional fees	$ 548	$ 575
Outside research and development services	4	61
Other	92	14
Accrued expenses, net	$ 644	$ 650

Other Long Term Liabilities

Other long term liabilities are comprised of the following (in thousands):

	December 31,	
	2018	2017
Deferred rent	$ 4	$ 46
Security deposit	12	12
Other long term liabilities, net	$ 16	$ 58

6. DEBT

Credit Facility

On October 17, 2014 (the "Closing Date"), the Company entered into the Credit Facility with the Lenders, pursuant to which the Lenders agreed, subject to certain conditions, to make term loans totaling up to $10.0 million available to the Company. The first $5.0 million term loan was funded on the Closing Date. A second term loan of $5.0 million was funded at the Company's request on July 23, 2015. The first and second term loans had annual interest rates of 7.95% and 8.01%, respectively. The repayment schedule provided for interest-only payments in arrears until November 2015, followed by consecutive equal monthly payments of principal and interest in arrears through the original maturity date, which was October 1, 2018 (the "Maturity Date").

On the Closing Date, the Company issued warrants to purchase up to an aggregate of 646 shares of common stock at an exercise price of $387.00 per share to the Lenders. On July 23, 2015, in connection with the funding of the second term loan, the Company issued additional warrants to purchase up to an aggregate of 508 shares of common stock at an exercise price of

$492.00 per share to the Lenders. The warrants were exercisable upon issuance and expire ten years from their dates of issuance. The warrants were classified in equity since they do not include provisions that would require the Company to repurchase its shares or cash settle, among other factors that would require liability classification. The fair value of the warrants at issuance of approximately $0.1 million was initially recorded as a discount to the principal balance and was being amortized over the life of the Credit Facility using the effective interest method. As a result of the prepayment of the Credit Facility in March 2017, the remaining discount was also written off.

On March 8, 2017, pursuant to the Ferring Asset Purchase Agreement, the Company repaid to the Lenders all amounts due and owed in full under the Credit Facility. Per the Credit Facility, the Company was subject to a prepayment fee of up to 3% since prepaying the outstanding balance of the term loans in full prior to the Maturity Date. Upon repayment of each term loan, the Company was also required to make a final payment to the Lenders equal to 6% of the original principal amount of each term loan. This final payment had been partially accreted over the life of the Credit Facility using the effective interest method. The final payment included the outstanding balance of the term loans in full as well as (i) a prepayment fee of approximately 2%, or $0.1 million, (ii) a final payment equal to 6% of the original principal amount of each term loan, or $0.6 million, and (iii) per diem interest of approximately $0.05 million, for a total payment of $6.6 million.

The Company's notes payable balance was zero for each of the years ended December 31, 2018 and 2017, respectively.

The Company recognized interest expense related to the Credit Facility of $0 and $0.1 million during the years ended December 31, 2018 and 2017, respectively. Although the extinguishment of the debt was a closing condition of the Ferring Asset Purchase Agreement, since the Credit Facility was related to corporate debt, the loss on extinguishment and related interest expense is presented on the consolidated statements of operations as continuing operations.

7. STOCKHOLDERS' EQUITY

Preferred Stock

The Company is authorized to issue 10.0 million shares of preferred stock, par value $0.001, of which 1.0 million shares are designated as Series A Junior Participating Preferred Stock, 800 are designated as Series B 8% Cumulative Convertible Preferred Stock, and 600 are designated as Series C 6% Cumulative Convertible Preferred Stock. No shares of preferred stock were outstanding as of December 31, 2018 or 2017.

Common Stock Offerings

September 2018 Financing

On September 20, 2018, the Company entered into a Securities Purchase Agreement (the "September 2018 SPA") with an investor (the "Purchaser") for net proceeds of approximately $1.1 million. Pursuant to the September 2018 SPA, the Company sold 153,333 shares of the Company's common stock, at a purchase price of $8.10 per share and warrants to purchase up to 115,000 shares of common stock, exercisable six months after issuance at an exercise price equal to $9.00 per share, in a private placement. In addition, the Company issued warrants to purchase up to 7,667 shares of common stock to H.C. Wainwright (the "September 2018 Placement Agent Warrants"). The September 2018 Placement Agent Warrants are exercisable six months after issuance at an exercise price of $10.125 per share, and expire five years from the initial exercise date. The Company also issued additional warrants to the Purchaser in an amount of 89,239 shares of common stock, exercisable six months after issuance at an exercise price equal to $12.00 per share (all warrants issued to the Purchaser in the September 2018 SPA, the "September 2018 Warrants"). The September 2018 Warrants are exercisable for five years from the initial exercise date. It is explicitly stated in the Form of Warrant for both the September 2018 Warrants and the September 2018 Placement Agent Warrants that under no circumstances would the Company be required to net cash settle the warrants. In connection with the September 2018 SPA, the Purchaser agreed to enter into a voting agreement with the Company to vote all of their respective shares of the Company's capital stock in favor of the adoption of the Merger Agreement.

The total initial $0.9 million fair value of the combined warrants was determined using the Black-Scholes option pricing model and was recorded to equity. The September 2018 Warrants and the September 2018 Placement Agent Warrants were classified as equity and valued using assumptions of an expected term of 5.5 years for each, a volatility of 107.3% for each, annual rate of dividends of 0% for each, and risk-free interest rates of 2.97% for each. Transaction costs of approximately $0.2 million were netted against the proceeds allocated to the common stock shares in equity.

In addition, pursuant to the terms of the September 2018 SPA, outstanding warrants to purchase up to 89,239 shares of common stock previously issued to and held by the Purchaser were cancelled at the closing, which occurred on September 24, 2018. The fair value of the exchange between the warrants previously issued and outstanding prior to the September 2018 SPA and those issued in replacement of those warrants was $0.6 million on the date of the modification, which resulted in a charge of $0.1 million to amendment of equity classified warrants on the consolidated statements of operations.

June 2018 Warrant Amendment

On June 22, 2018, the Company entered into the Subscription Agreement Amendment with the Investors, which, among other things, removed the Investors' preemptive rights with respect to future issuances of the Company's equity securities. Concurrently with the Subscription Agreement Amendment, the Company entered into the June 2018 Warrant Amendment with Sarissa Offshore regarding the 2015 and 2016 Warrants, pursuant to which the exercise price of the warrants was reduced from $21.30 to $12.60 per share. The amendment to the warrants resulted in a charge of approximately $17,000, which was recorded as amendment of equity classified warrants expense during the three months ended June 30, 2018.

March 2018 Warrant Amendment

In March 2018, the Company entered into the March 2018 Warrant Amendment with the holders of the 2015 and 2016 Warrants, which, among other things, (i) reduced the exercise price of the 2015 and 2016 Warrants from $264.00 to $21.30 per share, and (ii) amended certain provisions of the 2015 and 2016 Warrants such that they can no longer be net- cash settled. The fair value of the 2015 and 2016 Warrants on the date of the modification was $0.5 million, which resulted in a charge of $0.2 million to amendment of equity classified warrants on the consolidated statements of operations. Upon modification, the 2015 and 2016 Warrants were reclassified to stockholders' equity.

April 2018 Financing & Warrant Amendment

On April 2, 2018, the Company completed the April 2018 Financing for net proceeds of approximately $3.1 million, after deducting placement agent fees and other estimated offering expenses for the sale. Pursuant to the agreement, the Company sold 236,667 of the Company's 2018 Units. The April 2018 Warrants issued pursuant to the April 2018 Financing have an exercise price equal to $15.00 per share of common stock, and are only exercisable following the Company's announcement that it has received stockholder approval of the 2018 Charter Amendment and the effective date of the 2018 Charter Amendment. The April 2018 Warrants will expire five years from the date they are first exercisable. In addition, the Company issued the April 2018 Placement Agent Warrants to purchase up to 11,833 shares of common stock to H.C. Wainwright. The April 2018 Placement Agent Warrants are exercisable upon the announcement of the effectiveness of the 2018 Charter Amendment at an exercise price of $18.75 per share, and also expire five years from that date. It is explicitly stated in the Form of Warrant for both the April 2018 Warrants and the Placement Agent Warrants that under no circumstances may the shares be settled in cash.

The total initial $1.2 million fair value of the combined warrants was determined using the Black-Scholes option pricing model and was recorded to equity. The April 2018 Warrants and the April 2018 Placement Agent Warrants were classified as equity and valued using assumptions of expected terms of 5.12 years and 5.0 years, volatilities of 104.0% and 105%, respectively, annual rate of dividends of 0%, and risk-free interest rates of 2.55% for each. Transaction costs of approximately $0.7 million were netted against the proceeds allocated to the common stock shares in equity.

In connection with the April 2018 Financing, the Company entered into a warrant amendment with the holders of the Company's warrants to purchase common stock of the Company, issued in the September 2017 Financing. See below for details.

September 2017 Financing

On September 10, 2017, the Company entered into the September 2017 SPA with certain accredited investors for net proceeds of approximately $3.1 million. Pursuant to the agreement, the Company sold 71,220 shares of the Company's common stock at a purchase price of $51.90 per share and the September 2017 Warrants. The September 2017 Warrants were exercisable upon closing, or on September 13, 2017, at an exercise price equal to $50.10 per share of common stock and are exercisable for two and one-half years from that date. In addition, the Company issued the September 2017 Placement Agent Warrants. The September 2017 Placement Agent Warrants were exercisable upon closing at an exercise price of $64.80 per share, and also expire two and one-half years from the closing date.

The standalone fair value of the combined warrants was determined using the Black-Scholes option pricing model and was recorded to equity. The September 2017 Warrants and September 2017 Placement Agent Warrants were valued using assumptions of expected terms of 2.5 for each, volatilities of 110.4% for each, annual rate of dividends of 0.0% for each, and risk-free interest rates of 1.38% for each. The terms of the warrants state that under no circumstance may the shares be settled in cash. Therefore, the September 2017 Warrants and the September 2017 Placement Agent Warrants have been classified within stockholders' equity. The total proceeds from the private placement were allocated to the common stock and warrants on a relative fair values basis, with $2.8 million attributed to the common stock and $0.9 million attributed to the warrants. Transaction costs of approximately $0.6 million were netted against the proceeds and allocated to the common stock shares in equity.

In connection with the April 2018 Financing, the Company entered in the April 2018 Warrant Amendment, which (i) reduced the exercise price of the September 2017 Warrants and the September 2017 Placement Agent Warrants to $18.00 per share (the closing price of the Company's stock on March 27, 2018, the date of the amendment), and (ii) changed the date upon which such warrants become exercisable to the effective date of the 2018 Charter Amendment. The April 2018 Warrant Amendment resulted in a charge of approximately $0.1 million, which was recorded as amendment of equity classified warrants in the consolidated statement of operations for the year ended December 31, 2018.

April 2017 Financing & Warrant Amendment

On April 26, 2017, the Company completed the April 2017 Financing for net proceeds of approximately $5.9 million, after deducting the underwriting discounts and commissions and offering expenses payable by the Company. Pursuant to the underwriting agreement with H.C. Wainwright, the Company sold to H.C. Wainwright an aggregate of 167,667 units. Each unit consisted of one share of common stock and one warrant to purchase 0.75 of a share of common stock, sold at a public offering price of $42.00 per unit. The April 2017 Warrants became exercisable only following the Company's announcement that it has received stockholder approval of the effectiveness of the 2017 Charter Amendment and the 2017 Charter Amendment had become effective. The April 2017 Warrants were exercisable upon the effective date of the 2017 Charter Amendment on May 17, 2017, expire five years from such date and have an exercise price $46.50 per share of common stock. In connection with this transaction, the Company issued to H.C. Wainwright the 2017 Underwriter Warrants. The 2017 Underwriter Warrants have substantially the same terms as the 2017 Warrants, except that the 2017 Underwriter Warrants have a term of five years from April 20, 2017 and an exercise price of $52.50 per share. The terms of the April 2017 Warrants and the April 2017 Underwriter Warrants state that under no circumstance may the shares be settled in cash. Therefore, the April 2017 Warrants and the April 2017 Underwriter Warrants have been classified within stockholders' equity. The common shares, warrants and warrant shares were issued and sold pursuant to an effective registration statement on Form S-1, which was previously filed with the SEC and declared effective on April 20, 2017, and a related prospectus.

The total initial $2.9 million fair value of the combined warrants was determined using the Black-Scholes option pricing model and was recorded to equity. The warrants and Underwriter Warrants were valued using assumptions of expected terms of 5.06 and 5.0 years, respectively, volatilities of 88.3% and 88.7%, respectively, annual rate of dividends of 0.0% for each, and risk-free interest rates of 1.8% for each. Transaction costs of approximately $1.1 million were netted against the proceeds allocated to the common stock shares in equity.

Pursuant to the April 2017 Financing, the Company entered into a warrant amendment with the holders of the Company's warrants to purchase common stock of the Company, issued in the September 2016 Financing. See below for details.

September 2016 Financing

In September 2016, the Company completed the September 2016 Financing, which was a registered direct offering of 36,080 shares of common stock at a purchase price of $103.50 per share with a group of investors. Concurrently in a private placement, for each share of common stock purchased by each investor, such investor received from the Company an unregistered warrant to purchase three quarters of a share of common stock (the "2016 Private Placement Warrants"). Initially, the 2016 Private Placement Warrants had an exercise price of $135.00 per share, were exercisable six months from the initial issuance date, and would expire five and a half years from the initial issuance date. The aggregate gross proceeds from the sale of the common stock and warrants was approximately $3.7 million, and the net proceeds after deduction of commissions, fees and expenses was approximately $3.2 million. In connection with this transaction, the Company issued to the placement agent warrants to purchase up to 1,804 shares of common stock sold in this offering (the "2017 Placement Agent Warrants" and, together with the 2016 Private Placement Warrants, the "September 2016 Warrants"). The 2016 Placement Agent Warrants have substantially the same terms as the 2016 Private Placement Warrants, except that initially, the 2016 Placement Agent Warrants had an exercise price of $129.375 per share and would expire five years from the initial issuance date. Initially, the September 2016 Warrants were accounted for as a liability and fair-valued at the issuance date. Out of the total gross proceeds, $1.6 million was allocated to the 2016 Private Placement Warrants based on their fair value, and the rest was allocated to the common stock and recorded in equity. Also, in connection with the transaction, the Company incurred cash-based transaction costs of approximately $0.5 million and non-cash transaction costs of $0.1 million related to the fair value of the 2016 Placement Agent Warrants. These costs were allocated between the warrant liability and equity based on their relative values at the issuance date. The transaction costs that were allocated to the warrant liability of approximately $0.3 million were expensed and included in other financing expenses on the consolidated statements of operations and the transaction costs of approximately $0.4 million related to the common stock were netted against the proceeds allocated to the common stock shares in equity.

In connection with the April 2017 Financing, the Private Placement Warrants and the Placement Agent Warrants were amended pursuant to which, among other things, (i) the exercise price of the warrants was reduced to $46.50 per share (the exercise price of the warrants sold in the April 2017 Financing), (ii) the terms of the agreement were amended so that the shares cannot be cash settled under any circumstance, and (iii) the date upon which such warrants became exercisable was changed to the effective date of the Charter Amendment, or May 17, 2017 (the "April 2017 Warrant Amendment"). Based upon the amended terms of the agreement, the September 2016 Warrants were reclassified to stockholders' equity at the time of the April 2017 Warrant Amendment, or April 20, 2017. The fair value of the warrants on that date was $0.8 million, which resulted in a charge of $0.2 million to change in fair value of warrant liability on the consolidated statements of operations before reclassification to stockholders' equity during the second quarter of 2017.

July 2016 Aspire Common Stock Purchase Agreement

In July 2016, the Company and Aspire Capital entered into the Aspire Purchase Agreement, which provided that Aspire Capital was committed to purchase, if the Company chooses to sell and at the Company's discretion, an aggregate of up to $7.0 million of shares of the Company's common stock over the 24-month term of the Aspire Purchase Agreement. The Aspire Purchase Agreement could have been terminated at any time by the Company by delivering notice to Aspire Capital. On the Aspire Closing Date, the Company delivered to Aspire Capital a commitment fee of 5,063 shares of the Company's common

stock at a value of $0.6 million, in consideration for Aspire Capital entering into the Aspire Purchase Agreement. Additionally, on the Aspire Closing Date, the Company sold 8,439 shares of the Company's common stock to Aspire Capital for proceeds of $1.0 million. In connection with the transaction, the Company incurred cash transaction costs of approximately $0.1 million, which were netted against the proceeds in equity.

On any business day during the 24-month term of the Aspire Purchase Agreement, the Company has the right, in its sole discretion, to present Aspire Capital with a purchase notice (each, a "Purchase Notice") directing Aspire Capital to purchase up to 333 shares of the Company's common stock per business day, subject to certain limitations. The Company and Aspire Capital could have mutually agreed to increase the number of shares that could have been sold pursuant to a Purchase Notice to as much as an additional 6,667 shares of the Company's common stock per business day. The purchase price per share of the Company's common stock sold to Aspire Capital pursuant to a Purchase Notice was equal to the lower of (i) the lowest sales price of the Company's common stock on the purchase date or (ii) the average of the lowest three closing sales prices of the Company's common stock for the twelve business days prior to the purchase date. Under the Aspire Purchase Agreement, the Company and Aspire Capital shall not effect any sales on any purchase date where the closing sale price of the Company's common stock is less than $30.00.

Additionally, on any date on which (i) the Company submitted a Purchase Notice to Aspire Capital for at least 333 shares of the Company's common stock and (ii) the last closing trade price for the Company's common stock was higher than $90.00, the Company has the right, in its sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice (each, a "VWAP Purchase Notice") directing Aspire Capital to purchase an amount of the Company's common stock equal to up to 30% of the aggregate shares of the Company's common stock traded on the next business day (the "VWAP Purchase Date"), subject to certain limitations. The purchase price per share of the Company's common stock sold to Aspire Capital pursuant to a VWAP Purchase Notice shall be the lesser of (i) the closing sale price of the Company's common stock on the VWAP Purchase Date or (ii) 97% of the volume weighted average price of the Company's common stock traded on the VWAP Purchase Date, subject to certain limitations.

The Company also entered into a registration rights agreement with Aspire Capital, in which the Company agreed to file one or more registration statements, as permissible and necessary to register, under the Securities Act of 1933, as amended, the sale of the shares of the Company's common stock that have been and may be issued to Aspire Capital under the Purchase Agreement.

Pursuant to the Aspire Purchase Agreement, in no case could the Company issue more than 40,000 shares of the Company's common stock (which is equal to approximately 19.99% of the Company's common stock outstanding on the Aspire Closing Date) to Aspire Capital unless (i) the average price paid for all shares issued under the Aspire Purchase Agreement is at least $114.60 per share (a price equal to the most recent consolidated closing bid price of the Company's common stock prior to the execution of the Aspire Purchase Agreement) or (ii) the Company received stockholder approval to issue more shares to Aspire Capital. Since the inception of the Aspire Purchase Agreement through its termination, the Company has issued a total of 16,667 shares for gross proceeds of $1.2 million. Upon its termination, all of the reserve was available under the committed equity financing facility since the Company's stock price was above $3.00, subject to SEC limitations under the Form S-3 Registration Statement. However, in connection with the September 2016, April 2017 and April 2018 Financings, the Company agreed to not make any further sales under the Aspire Purchase Agreement for a period of twelve months following the date of each financing.

January 2016 Financing

In January 2016, the Company entered into subscription agreements with certain purchasers pursuant to which it agreed to sell an aggregate of 37,879 shares of its common stock and warrants to purchase up to an additional 18,939 shares of its common stock to the purchasers for an aggregate offering price of $10.0 million, to take place in separate closings (the "January 2016 Financing"). Each share of common stock was sold at a price of $264.00 and included one half of a warrant to purchase a share of common stock. During the first closing in January 2016, the Company sold an aggregate of 8,428 shares and warrants to purchase up to 4,214 shares of common stock for gross proceeds of $2.2 million. The remaining shares and warrants were sold in a subsequent closing in March 2016 for gross proceeds of $7.8 million following stockholder approval at a special meeting on March 2, 2016. The aggregate net proceeds, after deduction of fees and expenses of approximately $0.4 million, were approximately $9.6 million.

The warrants issued in connection with the January 2016 financing (the "January 2016 Warrants") occurred in separate closings in January 2016 and March 2016 and gave rights to purchase up to 18,939 total shares of the Company's common stock at an exercise price of $264.00 per share. The total initial $4.8 million fair value of the warrants on their respective closing dates was determined using the Black-Scholes option pricing model and was recorded as the initial carrying value of the common stock warrant liabilities. The warrants issued in January 2016 and March 2016 were initially valued using assumptions of expected terms of 7.0 years, volatilities of 101.9% and 99.4%, respectively, annual rate of dividends of 0.0%, and risk-free interest rates of 1.6% and 1.4%, respectively. Fees and expenses of approximately $0.2 million were allocated to the warrant liability and expensed in Other Financing Costs. The remaining expenses were netted against the proceeds allocated to the common stock shares in equity. The fair value of these warrants is remeasured at each financial reporting period with any changes in fair value recognized as a change in fair value of warrant liability in the accompanying consolidated statements of operations. These warrants became exercisable in July 2016 and September 2016 and have expiration dates of January 2023 and March 2023, respectively.

Pursuant to the January 2016 financing, the exercise price of warrants issued in connection with a financing in February 2015 were reduced from $546.00 per share to $264.00 per share. The modification to these warrants resulted in a charge to other financing costs of approximately $0.7 million in 2016. The exercise price of these warrants was further reduced in March 2018. See above for details.

Warrants

A summary of warrant activity during the year ended December 31, 2018 is as follows (share amounts in thousands):

	Common Shares Issuable upon Exercise		Weighted Average Exercise Price
Outstanding at December 31, 2017	236	$	117.30
Issued	342	$	12.30
Exercised	(35)	$	44.40
Cancelled	(107)	$	119.70
Outstanding as of December 31, 2018	437	$	20.70
Exercisable as of December 31, 2018	225	$	30.30

The following table shows the number of outstanding warrants by exercise price and date of expiration as of December 31, 2018 (share amounts in thousands):

Shares Issuable Upon Exercise	Exercise Price	Expiration Date
13	$ 18.00	March 2020
8	$ 52.50	April 2022
82	$ 46.50	May 2022
11	$ 12.60	January 2023
3	$ 21.30	January 2023
11	$ 12.60	March 2023
4	$ 21.30	March 2023
12	$ 18.90	March 2023
80	$ 15.00	May 2023
8	$ 10.14	March 2024
115	$ 9.00	March 2024
89	$ 12.00	March 2024
1	$ 387.00	October 2024
1	$ 492.00	July 2025
437		

8. EQUITY COMPENSATION PLANS

As of December 31, 2018, the Company has one share-based compensation plan, the 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, 2018, an aggregate of 67,731 shares of common stock were authorized under the 2012 Plan, of which 10,872 common shares were available for future grants.

Stock Options

A summary of stock option activity during the year ended December 31, 2018 is as follows (share amounts in thousands):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Total Aggregate Intrinsic Value
Outstanding as of December 31, 2017	12	$ 521.10	6.7	$ -
Granted	23	63.30		
Exercised	-	-		
Cancelled	(6)	183.90	-	-
Outstanding as of December 31, 2018	29	$ 230.10	7.8	$ -
Vested and expected to vest as of December 31, 2018	29	$ 230.10	7.8	$ -
Exercisable as of December 31, 2018	15	$ 375.00	6.8	$ -

As of December 31, 2018 and 2017, there were 15,076 and 9,777 options exercisable, respectively. There were no options exercised during either of the years ended December 31, 2018 and 2017. The total fair value of options vested during the years ended December 31, 2018 and 2017 was $1.0 million and $0.8 million, respectively.

Restricted Stock Units

A summary of restricted stock unit activity during the year ended December 31, 2018 is as follows:

	Number of Shares		Weighted Average Grant Date Fair Value
Nonvested as of December 31, 2017	24	$	47.10
Granted	-	$	-
Vested	(14)	$	49.50
Forfeited	(1)	$	39.60
Nonvested as of December 31, 2018	9	$	43.80

The total fair value of awards vested during the years ended December 31, 2018 and 2017 was $0.3 million and $0.4 million for each year, respectively.

Share-Based Compensation

The value of restricted stock unit grants is calculated based upon the closing stock price of the Company's common stock on the date of the grant. For stock options granted to employees and directors, the Company recognizes compensation expense based on the grant-date fair value over the requisite service period of the awards, which is the vesting period. The Company estimates the fair value of each option award on the date of grant using the Black-Scholes option pricing model.

The following table presents the weighted average assumptions used by the Company to estimate the fair value of stock option grants using the Black-Scholes option-pricing model, as well as the resulting weighted average fair values at their issuance dates during the year ended December 31, 2018. No stock options were granted during the year ended December 31, 2017.

	2018
Risk-free interest rate	2.3%-2.3%
Volatility	98%-105%
Dividend yield	-- %
Expected term	5-6.08 years
Forfeiture rate	11.33%
Weighted average fair value	$ 49.88

Expected Volatility. The Company uses analysis of historical volatility to determine the expected volatility of its stock options.

Expected Term. The expected life assumptions are based on the simplified method due to the lack of sufficient history as set forth in SEC's Staff Accounting Bulletin Topic 14.

Risk-Free Interest Rate. The interest rate used in valuing awards is based on the yield at the time of grant of a United States Treasury security with an equivalent remaining term.

Dividend Yield. The Company has never paid cash dividends, and does not currently intend to pay cash dividends, and thus has assumed a 0% dividend yield.

Pre-Vesting Forfeitures. Estimates of pre-vesting option forfeitures are based on the Company's experience. The Company adjusts its estimate of forfeitures over the requisite service period based on the extent to which actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures are recognized through a cumulative catch-up adjustment in the period of change and also impact the amount of compensation expense to be recognized in future periods. Adjustments have not been significant to date.

As of December 31, 2018, there was $0.6 million in unrecognized compensation cost related to non-vested stock options expected to be recognized over a weighted average period of 2.7 years. As of December 31, 2018, there was $0.06 million in unrecognized compensation cost related to non-vested restricted stock units expected to be recognized over a weighted average period of 0.08 year. In addition, the Company has $0 in unrecognized compensation cost related to performance restricted stock units. The Company records expense related to its performance RSUs based on the probability of occurrence, which is reassessed each quarter.

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,	
	2018	2017
Research and development	$ 336	$ 227
General and administrative	965	911
	$ 1,301	$ 1,138

9. RELATED PARTY TRANSACTIONS

The Company had the following related party transaction for 2018:

IRRAS AB

IRRAS AB ("IRRAS") is a commercial stage medical technology company of which a current director of the Company, Kleanthis G. Xanthopoulos, Ph.D., is currently 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 has a term of two years and aggregate payments due to the Company of approximately $0.3 million. 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 current corporate headquarters (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 approximate fair value.

10. INCOME TAXES

The Company has incurred losses since inception, which have generated net operating loss carryforwards and capital loss carryforwards of approximately $118.4 million and $9.8 million for federal and California income tax purposes, respectively. These carryforwards are available to offset future taxable income and expire beginning in 2019 through 2037 for federal income tax purposes and beginning in 2030 through 2033 for California income tax purposes. Also, Federal net operating loss carryforwards that were generated in 2018 have an indefinite carryforward period. In addition, the Company has research and development tax credit carryforwards for federal and state income tax purposes as of December 31, 2018 of $1.8 million and $1.0 million, respectively. The federal credits will begin to expire in 2019 unless utilized and the state credits have an indefinite life.

Utilization of the loss carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required under Internal Revenue Code Section 382 ("Section 382"), as well as similar state and foreign provisions. These ownership changes may limit the amount of loss carryforwards that can be utilized annually to offset future taxable income. In general, an "ownership change" as defined by Section 382 results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage

points of the outstanding stock of a company by certain stockholders or public groups. Since the Company's formation, the Company has raised capital through the issuance of capital stock on several occasions which, combined with the purchasing stockholders' subsequent disposition of those shares, likely resulted in such an ownership change, or could result in an ownership change in the future upon subsequent disposition.

During the first quarter of 2017, the Company completed a study to assess whether an ownership change occurred and determined that there have been multiple ownership changes since the Company's formation. As a result, utilization of the loss carryforwards are subject to an annual limitation under Section 382, which was determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term, tax-exempt rate. These limitations resulted in the expiration of the majority of the Company's loss carryforwards. These loss carryforwards that have expired due to these limitations have been removed from deferred tax assets with a corresponding reduction of the valuation allowance with no net effect on income tax expense or the effective tax rate. Despite the assessment completed during the first quarter of 2017, additional ownership changes may have occurred subsequent to the completion of the study, which would continue to limit utilization of any future loss carryforwards including as a result of the Merger which occurred subsequent to the Company's year end.

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

	December 31,	
	2018	2017
Net operating tax loss and capital loss carryforwards	$ 25,549	$ 23,463
Capitalized research and development costs	4,194	4,620
Research and development tax credits	1,937	1,923
Other accruals and reserves	494	721
Basis of intangible assets	3,136	3,658
Total deferred tax asset	35,310	34,385
Less valuation allowance	(35,310)	(34,385)
Net deferred tax asset	$ -	$ -

The federal net operating loss carryforwards and tax credit carryforwards resulted in a noncurrent deferred tax asset as of December 31, 2018 and 2017 of approximately $27.5 million and $25.4 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 2015 to 2018 are still open and subject to audit. In addition, net operating losses and capital 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, 2018 and 2017, 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, 2018 and 2017, are as follows (in thousands):

	Year Ended December 31,	
	2018	2017
Beginning balance	$ 713	$ 3,047
Change in current period positions	13	34
Change in prior period positions	(8)	(2,368)
Ending balance	$ 718	$ 713

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, 2018 and 2017, are as follows:

	Year Ended December 31,	
	2018	2017
Federal statutory tax rate	(21)%	(34)%
Change in rate	- %	165 %
Valuation allowance	10 %	(360)%
Deferred tax true-ups	5 %	227 %
Revaluation of warrants	- %	2 %
Permanent differences	7 %	1 %
Tax credits	(1)%	(1)%
Income tax expense	- %	- %

US Tax Reform

On December 22, 2017, the 2017 Tax Cuts and Jobs Act (Tax Act) was enacted into law and the new legislation contains several key tax provisions that affected the Company, including a reduction of the corporate income tax rate to 21% effective January 1, 2018, among others. The Company is required to recognize the effect of the tax law changes in the period of enactment, such as determining the transition tax, remeasuring the Company's U.S. deferred tax assets and liabilities, as well as reassessing the net realizability of the Company's deferred tax assets and liabilities. In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (SAB 118), which allowed the Company to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. As a result, the Company previously provided a provisional estimate of the effect of the Tax Act in the Company's financial statements. In the fourth quarter of 2018, the Company completed its analysis to determine the effect of the Tax Act and recorded no material adjustments as of December 31, 2018.

11. COMMITMENTS AND CONTINGENCIES

Operating Leases

In December 2011, the Company entered into a five-year lease agreement for its headquarters in San Diego, California expiring December 31, 2016. In December 2015, the Company amended the lease agreement to extend the term through December 31, 2020. The Company has 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 received a total of a six-month base rent abatement from the lease agreement and amendment. This abatement is recoverable by the landlord on a straight-line amortized basis over 60 months should the Company terminate the lease early for any reason.

In 2018, the Company subleased excess capacity in its San Diego headquarters to a subtenant under a non-cancellable lease. The sublease has a term of two years and aggregate payments due to the Company of approximately $0.3 million. On October 30, 2018, the Company amended and restated its sublease, commencing January 1, 2019, pursuant to which the Company agreed to sublease the remainder of its San Diego headquarters, which satisfied a closing condition related to the merger. The amended and restated sublease has a term of one year and provides for aggregate payments due to the Company of approximately $0.4 million, which approximate fair value.

For the years ended December 31, 2018 and 2017, rent expense totaled $0.3 million and $0.3 million, respectively.

Future minimum rental payments under operating leases as of December 31, 2018 are as follows (in thousands):

2019	$	374
2020		32
Total	$	406

Certain employees have agreements that provide for severance compensation in the event of termination or a change in control. These agreements can provide for a severance payment of up to 18 months of base salary and bonus in effect at the time of termination and continued health benefits at the Company's cost for up to 18 months.

Litigation

The Company 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. The Company intends to vigorously defend its interests in these matters and does not expect that the resolution of these matters will have a material adverse effect on its 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.

A complaint was filed in the Supreme Court of the State of New York by Laboratoires Majorelle SAS and Majorelle International SARL ("Majorelle") on July 25, 2017 naming Apricus Biosciences, Inc., NexMed (U.S.A.), Inc. and Ferring as defendants. The complaint sought a declaratory judgment that a non-compete provision in a license agreement between the Company and Majorelle, dated November 12, 2013, was unenforceable and made other claims relating to invalidity of the Company's assignment of the license agreement to Ferring under the Ferring Asset Purchase Agreement. The complaint also alleged breach of contract, fraudulent inducement, misrepresentation and unjust enrichment relating to a separate supply agreement between the Company and Majorelle. In addition to declaratory relief, Majorelle sought damages in excess of $1.0 million, disgorgement of profits and attorney's fees. On August 30, 2017, the Company and NexMed removed the case to federal district court in the Southern District of New York. Majorelle filed an amended complaint on October 16, 2017. The Company filed a motion to dismiss all claims in the amended complaint on December 5, 2017. The Company filed a motion to dismiss all claims in the amended complaint on December 5, 2017. On September 21, 2018, the Court granted the Company's motion to dismiss Majorelle's federal antitrust claim and dismissed the entire case.

12. SUBSEQUENT EVENT

Merger

On January 24, 2019, the Company completed the Merger with STI, pursuant to which Merger Sub merged with and into STI, with STI surviving as the Company's wholly-owned subsidiary. See note 2 to the consolidated financial statements above for additional information on the Merger.

Severance

The Company paid approximately $1.8 million in January 2019 pursuant to certain employment agreements that triggered upon the completion of the Merger with STI.

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 Securities Exchange Act of 1934, as amended (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, 2018. Based on this evaluation, our CEO concluded that our disclosure controls and procedures were effective as of December 31, 2018.

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 its 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, 2018 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, 2018, our internal control over financial reporting was effective. Because we are a smaller reporting company, BDO, an independent registered public accounting firm, is not required to attest to or issue a report on the effectiveness of our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

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

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the most recent fiscal quarter ended December 31, 2018, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Name	Age	Position
Non-Employees Directors		
Richard Pascoe[1]	55	Director
Robin L. Smith, M.D.[2][3]	53	Director
Daniel J. O'Connor[1][2]	53	Director
Brian Lian, Ph.D.[1][2][3]	53	Director
Executive Officers		
Raj Mehra, Ph.D.	59	Chairman, Chief Executive Officer, President & Interim Chief Financial Officer

[1] Member of the Corporate Governance/Nominating Committee.

[2] Member of the Audit Committee.

[3] Member of the Compensation Committee.

There are no family relationships between any of our directors or executive officers.

Board of Directors

Richard W. Pascoe has been a director since March 2013. He is the Chair of our Corporate Governance/Nominating Committee. He has served as the Chairman and Chief Executive Officer of Histogen Inc., a private regenerative medicine company, since January 2019. He previously served as our Chief Executive Officer from March 2013 to January 2019, our Secretary from February 2015 to January 2019, and our Principal Financial Officer and Principal Accounting Officer from December 2016 to January 2019. He joined Seelos following the merger of Somaxon Pharmaceuticals, Inc. with Pernix Therapeutics Holdings, Inc. Mr. Pascoe was the Chief Executive Officer of Somaxon from August 2008 until joining Seelos and was responsible for the FDA approval of Somaxon's lead drug Silenor®. Prior to Somaxon, Mr. Pascoe was with ARIAD Pharmaceuticals, Inc., a specialty pharmaceutical company where he was most recently Senior Vice President and Chief Operating Officer. Prior to joining ARIAD in 2005, Mr. Pascoe held a series of senior management roles at

King Pharmaceuticals, Inc. (acquired by Pfizer Inc.), including Senior Vice President positions in both marketing and sales, as well as Vice President positions in both international sales and marketing and hospital sales. Prior to King, Mr. Pascoe was in the commercial groups at Medco Research, Inc. (acquired by King), COR Therapeutics, Inc. (acquired by Millennium Pharmaceuticals Inc., the Takeda Oncology Company), B. Braun Interventional and The BOC Group. Mr. Pascoe is a member of the board of directors of KemPharm, Inc., as well as a member of the company's audit and compensation committees and its lead independent director. He serves as a member of the board of directors of the Johnny Mac Soldiers Fund, a charity for military veterans. Mr. Pascoe is also a member of the board of directors of BIOCOM, as well as its Chair Elect. Mr. Pascoe served as a Commissioned Officer with the U.S. Army 24th Infantry Division during Operations Desert Shield and Storm where he earned a Bronze Star Medal. He continues to serve as a Civilian Aid to the Secretary of the Army. He is a graduate of the United States Military Academy at West Point where he received a B.S. degree in Leadership.

Dr. Robin L. Smith has been a director since January 2019. She is a member of our Audit Committee and a member of our Compensation Committee. Dr. Smith is a global thought leader in the regenerative medicine industry, one of the fastest growing segments of modern-day medicine. She received her M.D. from Yale University and an M.B.A. from the Wharton School of Business. She served as CEO of Caladrius Biosciences, Inc. (formerly NeoStem Inc.) (Nasdaq: CLBS), from 2006 to 2015. In 2007, Dr. Smith founded The Stem for Life Foundation (SFLF), a nonpartisan, 501(c)(3) educational organization devoted to fostering global awareness of the potential for regenerative medicine to treat and cure a range of deadly diseases and debilitating medical conditions, as opposed to merely treating their symptoms, and has served as Chairman of the Board and President of the Stem for Life Foundation since its inception and now the expanded Cura Foundation. Dr. Smith was appointed as Clinical Associate Professor, Department of Medicine at the Rutgers, New Jersey Medical School in 2017. In addition, Dr. Smith has extensive experience serving in executive and board level capacities for various medical enterprises and healthcare-based entities. She has served on the Board of Directors of Rockwell Medical (Nasdaq: RMTI) since June 2016 and ProLung Inc. since February 2017, and has been Chairman of the Board of Mynd Analytics (Nasdaq: MYND) since August 2015. She has also served on the advisory board of Hooper Holmes Inc. (OTCQX: HPHW) since March 2017 and has been co-chairman of the Life Sci advisory board on gender diversity since April 2016. She has been Vice President and a member of the Board of Directors of the Science and Faith STOQ Foundation in Rome since 2015 and has served on Sanford Health's International Board since 2016 and the Board of Overseers at the NYU Langone Medical Center in New York since 2014. She served on the Board of Trustees of the NYU Langone Medical Center from 2006 to 2014, was Chairman of the Board of Directors for the New York University Hospital for Joint Diseases from 2004 to 2010 and was on the board of directors of Signal Genetics, Inc. (Nasdaq: SGNL) from July 2014 to February 2016 and BioXcel Corporation from August 2015 to June 2017.

Daniel J. O'Connor, J.D. has been a director since January 2019. He is the Chair of our Audit Committee and a member of our Corporate Governance/Nominating Committee. He is currently Chief Executive Officer and a director of OncoSec Medical Incorporated. Prior to that, Mr. O'Connor served as President, Chief Executive Officer, Director and in other senior roles at Advaxis, Inc., a cancer immunotherapy company, from January 2013 until his resignation in July 2017. Prior to that, Mr. O'Connor was Senior Vice President and General Counsel for BRACCO Diagnostics Inc., a diagnostic imaging company, from 2008 until 2012; Senior Vice President, General Counsel and Secretary for ImClone Systems Incorporated, a biopharmaceutical company, from 2002 until 2008; and General Counsel at PharmaNet (now inVentiv Health Clinical), a clinical research company, from 1998 until 2001. Mr. O'Connor is a 1995 graduate of the Pennsylvania State University's Dickinson School of Law in Carlisle, Pennsylvania and currently serves as an Entrepreneur Trusted Advisor to its Dean. He graduated from the United States Marines Corps Officer Candidate School in 1988 and was commissioned as an officer in the U.S. Marines, attaining the rank of Captain while serving in Saudi Arabia during Operation Desert Shield. Mr. O'Connor is currently the Vice Chairman of the Board of the Trustees of BioNJ. In October 2017, Mr. O'Connor was appointed to the New Jersey Biotechnology Task Force by its Governor, and he was formerly a New Jersey criminal prosecutor.

Brian Lian, Ph.D. has been a director since January 2019. He is the Chair of our Compensation Committee, a member of our Audit Committee and a member of our Corporate Governance/Nominating Committee. He is currently President and Chief Executive Officer and a Director of Viking Therapeutics, Inc. (Nasdaq: VKTX), a biopharmaceutical company. Dr. Lian has over 15 years of experience in the biotechnology and financial services industries. Prior to joining Viking, he was a Managing Director and Senior Research Analyst at SunTrust Robinson Humphrey, an investment bank, from 2012 to 2013. At SunTrust Robinson Humphrey, he was responsible for coverage of small and mid-cap biotechnology companies with an emphasis on companies in the diabetes, oncology, infectious disease and neurology spaces. Prior to SunTrust Robinson Humphrey, he was Managing Director and Senior Research Analyst at Global Hunter Securities, an investment bank, from 2011 to 2012. Prior to Global Hunter Securities, he was Senior Healthcare Analyst at The Agave Group, LLC, a registered investment advisor, from 2008 to 2011. Prior to The Agave Group, he was an Executive Director and Senior Biotechnology Analyst at CIBC World Markets, an investment bank, from 2006 to 2008. Prior to CIBC, he was a research scientist in small molecule drug discovery at Amgen, a biotechnology company. Prior to Amgen, he was a research scientist at Microcide Pharmaceuticals, a biotechnology company. Dr. Lian holds an MBA in accounting and finance from Indiana University, an MS and Ph.D. in organic chemistry from The University of Michigan, and a BA in chemistry from Whitman College.

Executive Officers

Dr. Raj Mehra has been our President, Chief Executive Officer, Interim Chief Financial Officer and Chairman of the Board of Directors since January 2019. Prior to founding Seelos, Dr. Mehra spent nine years at Auriga USA, LLC as a Managing Director focused on private and public equity investments in global healthcare companies. Prior to Auriga, Dr. Mehra was the sector head for healthcare equity investments at Bennett Lawrence Management, LLC in New York. He also founded and managed a long-short equity hedge fund at Weiss, Peck & Greer LLC. Dr. Mehra started his career as an investment professional at Cowen Asset Management, LLC. Dr. Mehra holds M.S., M.Phil., Ph.D., JD and MBA degrees from Columbia University in New York. He is also a graduate of Indian Institute of Technology, Kanpur, where he was ranked first in his class.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act requires our executive officers, directors and persons who beneficially own greater than 10% of a registered class of its equity securities to file certain reports with the SEC with respect to ownership and changes in ownership of the our common stock and our other equity securities.

To our knowledge, based solely on our review of the copies of such reports filed with the SEC, our officers, directors and greater than 10% stockholders timely complied with these Section 16(a) filing requirements during the fiscal year ended December 31, 2018.

Code of Ethics

We have adopted a Code of Ethics, as amended, that applies to our Chief Executive Officer and to all of our other officers, directors and employees. The Code of Ethics is available in the Corporate Governance section of the Investors page on our website at www.seelostherapeutics.com. We will disclose future amendments to, or waivers from, certain provisions of our code of ethics, if any, on the above website within four business days following the date of such amendment or waiver.

Audit Committee

Our audit committee currently consists of Daniel J. O'Connor, J.D. (Chair), Brian Lian, Ph.D. and Dr. Robin L. Smith. All are non-employee directors and are considered independent under the applicable independence standard promulgated by Nasdaq and the SEC. Our Board of Directors has currently designated Mr. O'Connor as an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K. We believe that the audit committee members are capable of analyzing and evaluating our financial statements and understanding internal controls over financial reporting.

Corporate Governance/Nominating Committee

Our Corporate Governance/Nominating Committee currently consists of Richard W. Pascoe (Chair), Daniel J. O'Connor, J.D. and Brian Lian, Ph.D. Except for Mr. Pascoe, all are non-employee directors and are considered independent under the applicable independence standard promulgated by Nasdaq and the SEC. Mr. Pascoe is currently serving as a non-independent member of this committee pursuant to the exceptional and limited circumstances exemption under Nasdaq Listing Rule 5605(e)(3). Nasdaq Listing Rule 5605(e)(3) permits one non-independent director to serve on this committee for a period of up to two years if our Board of Directors has determined that it is required by our best interests and the best interests of our stockholders. Mr. Pascoe served as our Chief Executive Officer March 2013 to January 2019, our Secretary from February 2015 to January 2019, and our Principal Financial Officer and Principal Accounting Officer from December 2016 to January 2019. While his employment terminated in January 2019, and while Mr. Pascoe currently receives no compensation from us other than as a non-employee director, Mr. Pascoe is deemed not to be an independent director pursuant to Nasdaq Listing Rule 5605 for three years following termination of his employment. Nevertheless, pursuant to Nasdaq Listing Rule 5605(e)(3), our Board of Directors has determined that, due to Mr. Pascoe's experience and expertise in the biopharmaceuticals industry, he is uniquely suited to assist our Board of Directors in identifying qualified candidates for director and for membership on our committees, to assist our Board of Directors in its review of its performance, and to otherwise serve on our Corporate Governance/Nominating Committee, and it is in our best interests and the best interests of our stockholders for him to serve as a member of our Corporate Governance/Nominating Committee.

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth the compensation paid by us during the years ended December 31, 2018 and 2017 to (1) our principal executive officer during fiscal year 2018 and (2) the other two most highly paid executive officers who were serving as executive officers as of December 31, 2018 (collectively our "Named Executive Officers"):

Name and Position	Year	Salary	Bonus (4)	Stock Awards (5)	Option Awards (6)	Non-Equity Incentive Plan Compensation (7)	All Other Compensation	Total
Richard W. Pascoe,	2018	$ 487,396	$ -	$ -	$ 516,950	$ -	$ 13,728	$ 1,018,074
Former Chief Executive Officer, Secretary and Director (1)	2017	$ 487,396	$ 97,479	$ 64,000	$ -	$ 176,681	$ 13,036	$ 838,592
Brian T. Dorsey, Former Senior Vice	2018	$ 319,300	$ -	$ -	$ 126,600	$ -	$ 13,115	$ 459,015
President, Chief Development Officer (2)	2017	$ 319,300	$ 63,860	$ 48,000	$ -	$ 92,597	$ 12,788	$ 536,545
Neil Morton, Former Senior Vice	2018	$ 275,000	$ -	$ -	$ 126,600	$ -	$ 12,636	$ 414,236
President, Chief Business Officer (3)	2017	$ 275,000	$ 55,000	$ 48,000	$ -	$ 79,750	$ 12,006	$ 469,756

1. Mr. Pascoe's employment terminated on January 24, 2019. Mr. Pascoe's all other compensation in 2018 includes $11,000 for our matching and profit sharing contribution to the 401(k) plan and $2,727.84 in life insurance premiums.

2. Mr. Dorsey's employment terminated on August 30, 2018. Mr. Dorsey's all other compensation in 2018 includes $10,635 for our matching and profit sharing contribution to the 401(k) plan and $2,480.16 in life insurance premiums.

3. Mr. Morton's employment terminated on January 24, 2019. Mr. Morton's all other compensation in 2018 includes $11,000 for our matching and profit sharing contribution to the 401(k) plan and $1,636.08 in life insurance premiums.

4. Represents the dollar amount of the special one-time bonus approved and ratified by the Compensation Committee on June 1, 2017, which was intended to recognize the efforts of such executives related to the sale of our ex-U.S. Vitaros business.

5. Represents the grant date fair value of the stock awards granted in the applicable fiscal year, computed in accordance with FASB ASC Topic 718. For stock options granted to employees and directors, we recognizes compensation expense based on the grant-date fair value over the requisite service period of the awards, which is the vesting period. We estimate the fair value of each option award on the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions: risk-free interest rate: 2.27% - 2.29%; volatility: 98.09& - 105.01%; dividend yield: -% and expected term (in years): 5.00 - 6.08.

   With respect to the performance-based RSUs granted to Mr. Pascoe, Mr. Dorsey and Mr. Morton in January 2017 and June 2017, the amounts in these columns include the grant-date fair value of such stock awards based upon the probable outcome of such conditions, all of which were not deemed probable of achievement. The full grant date fair value of these stock awards, assuming full achievement of the performance conditions to which such stock awards are subject, is as follows: Mr. Pascoe, $218,000; Mr. Dorsey, $163,500; and Mr. Morton, $163,500. A portion of the stock awards shown in the 2017 column of the table above relates to performance RSUs that were granted in June 2017 and vested upon resubmission of our Vitaros New Drug Application in August 2017

6. Represents the grant date fair value of the stock option awards granted in 2018, calculated in accordance with FASB ASC Topic 718, excluding the effect of estimated forfeitures. These figures do not reflect the amortized compensation expense or value received by the officer in the year indicated or that may be received by the officer with respect to such equity awards.

7. Represents the bonuses paid to the Named Executive Officers in cash in 2018 for 2017 performance pursuant to our' annual incentive program. There were no bonuses paid to Named Executive Officers in 2019 for 2018 performance pursuant to our annual incentive program.

Narrative Disclosure to Summary Compensation Table

Base Salary

In general, base salaries for our Named Executive Officers are approved by the Compensation Committee and are initially established through arm's length negotiation at the time the executive is hired, taking into account such executive's qualifications, experience, prior salary and market pay levels. Base salaries of our Named Executive Officers are approved and reviewed annually by our Compensation Committee and adjustments to base salaries are based on the scope of an executive's responsibilities, individual contribution, prior experience and sustained performance. Decisions regarding salary increases may take into account an executive officer's current salary, equity ownership, and the amounts paid to an executive officer's peers inside our company by conducting an internal analysis, which compares the pay of an executive officer to other members of the management team. Base salaries are also reviewed in the case of promotions or other significant changes in responsibility. Base salaries are not automatically increased if the Compensation Committee believes that other elements of the Named Executive Officer's compensation are more appropriate in light of our stated objectives. This strategy is consistent with our intent of offering compensation that is both cost-effective, competitive and contingent on the achievement of performance objectives.

Our Named Executive Officers did not receive base salary increases in 2019, 2018 or 2017.

Annual Cash Incentive

We also generally provide executive officers with annual performance-based cash bonuses, which are specifically designed to reward executives for overall performance in a given year. Corporate goals are established by the Compensation Committee with input from senior management and approved by the full Board. For 2018, the Compensation Committee considered compensation criteria but declined to formally establish corporate goals and no annual cash bonus amounts were paid to our Named Executive Officers for 2018 in light of the completion of the Merger

Equity Compensation

The Compensation Committee considers equity incentives to be important in aligning the interests of our executive officers with those of our stockholders. As part of our pay-for- performance philosophy, our compensation program tends to emphasize the long-term equity award component of total compensation packages paid to our executive officers.

Because vesting is based on continued employment, our equity-based incentives also encourage the retention of our Named Executive Officers through the vesting period of the awards. In determining the size of the long-term equity incentives to be awarded to our Named Executive Officers, we take into account a number of internal factors, such as the relative job scope, the value of existing long-term incentive awards, individual performance history, prior contributions to us and the size of prior grants. For 2018, while our Compensation Committee reviewed competitive market data prepared by Radford in connection with its grant of long-term equity incentive awards to the Named Executive Officers, such awards were not determined by reference to any specific target level of compensation or benchmarking. Based upon these factors, the Compensation Committee determines the size of the long-term equity incentives at levels it considers appropriate to create a meaningful opportunity for reward predicated on the creation of long-term stockholder value.

To reward and retain our Named Executive Officers in a manner that best aligns employees' interests with stockholders' interests, we use stock options and restricted stock unit awards as the primary incentive vehicles for long-term compensation. We believe that stock options and restricted stock unit awards are effective tools for meeting our compensation goal of increasing long-term stockholder value by tying the value of the stock to our future performance. Because employees are able to profit from stock options only if our stock price increases relative to the stock option's exercise price, we believe stock options provide meaningful incentives to employees to achieve increases in the value of our stock over time.

We use stock options and restricted stock unit awards to compensate our Named Executive Officers both in the form of initial grants in connection with the commencement of employment and annual refresher grants. Annual grants of equity awards are typically approved by the Compensation Committee during the first quarter of each year. While we intend that the majority of equity awards to our employees be made pursuant to initial grants or our annual grant program, the Compensation Committee retains discretion to grant equity awards to employees at other times, including in connection with the promotion of an employee, to reward an employee, for retention purposes or for other circumstances recommended by management or the Compensation Committee.

The exercise price of each stock option grant is the fair market value of our common stock on the grant date. Time-based stock option awards granted to our Named Executive Officers generally vest over a four-year period as follows: 25% of the shares underlying the option vest on the first anniversary of the date of the vesting commencement date and the remainder of the shares underlying the option vest in equal monthly installments over the remaining 36 months thereafter. From time to time, our Compensation Committee may, however, determine that a different vesting schedule is appropriate. We do not have any stock ownership requirements for our Named Executive Officers.

2018 Awards Granted - Time-Based Stock Options

In January 2018, the Board, based upon a recommendation by the Compensation Committee, awarded annual stock options to our Named Executive Officers based on its review of the foregoing factors and comparable company information. These awards are described in detail in the "Outstanding Equity Awards as of December 31, 2018" table below. The stock options are subject to our standard time-based four-year vesting schedule described above.

The Board's determination regarding each Named Executive Officer's annual award amount was not based on any quantifiable factors, but instead was based on the Compensation Committee's subjective analysis of the award levels the Compensation Committee deemed appropriate for each executive in light of various factors, including the fact that each executive's base salary remained below the 50th percentile for our peer group for 2015. The final award levels, however, were entirely based on the Compensation Committee's subjective analysis of these general factors and internal pay equity considerations.

Employee Benefit Program

Executive officers, including the Named Executive Officers, are eligible to participate in all of our employee benefit plans, including medical, dental, vision, group life, disability and accidental death and dismemberment insurance, in each case on the same basis as other employees, subject to applicable law. We also provide vacation and other paid holidays to all employees, including executive officers. These benefit programs are designed to enable us to attract and retain our workforce in a competitive marketplace. Health, welfare and vacation benefits ensure that we have a productive and focused workforce through reliable and competitive health and other benefits.

Our retirement savings plan (401(k) Plan) is a tax-qualified retirement savings plan, pursuant to which eligible employees can begin to participate immediately upon employment. The 401(k) Plan elective deferrals and employer contributions are subject to compensation limitations and annual maximum contribution limits as governed by Internal Revenue Service. Employees are eligible to defer up to 100% of compensation and we make safe harbor matching contributions of 100% match of first 3% of compensation contributed, then 50% match of next 2% of compensation contributed.

Outstanding Equity Awards as of December 31, 2018

The following table shows information regarding our outstanding equity awards as of December 31, 2018 for the Named Executive Officers:

	Option Awards (1)					Stock Awards			
Name	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Non-Exercisable (#)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned shares, Units or Other Rights That Have Not Vested (#) (4)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($) (5)
Richard W.	-	8,166	-	$ 63.30	1/3/2028	-	$ -	3,916	$ 22,562
Pascoe	3,000	-	-	$ 753.00	3/18/2023				
	979	20	-	$ 429.00	1/29/2025				
	1,146	520	-	$ 333.00	3/15/2026				
Brian T. Dorsey	2,000	-	-	$ 63.30	1/3/2028	-	$ -	-	$ -
	1,000	-	-	$ 339.00	12/1/2024				
	666	-	-	$ 333.00	3/15/2026				
Neil Morton	-	2,000	-	$ 63.30	1/3/2028	-	$ -	2,666	$ 15,358
	400	-	-	$ 696.00	3/20/2024				
	266	-	-(3)	$ 696.00	3/20/2024				
	195	4	-	$ 429.00	1/29/2025				
	194	88	-	$ 333.00	3/15/2026				
	366	183	-	$ 171.00	4/1/2026				

1. Except as otherwise noted, all stock options have a term of ten years from the date of grant and vest over four years, with 25% of the shares subject to the options vesting on the first anniversary of the date of grant and the remainder vesting in 36 monthly tranches thereafter. For a description of the accelerated vesting provisions applicable to the stock options granted to the Named Executive Officer, see "Payments Upon Termination or Change in Control" below. The vesting of all of Mr. Dorsey's options accelerated upon his termination of employment on August 30, 2018, pursuant to the terms of his release agreement.

2. The vesting of all of Mr. Dorsey's restricted stock units accelerated upon his termination of employment on August 30, 2018, pursuant to the terms of his release agreement.

3. Represents performance-based stock options that vested based on our initiation of one or more Phase II or later clinical trials of assets approved by the Board (each, a "Qualifying Trial") on or before December 31, 2015, as follows: (1) 25% of the underlying shares vested upon the First Vesting Date (e.g., the enrollment of the first patient in the first Qualifying Trial), which occurred as a result of the randomization and first dosing of the first RayVa Phase 2a patient in December 2014; 1/96th of the total number of shares subject to the option vested monthly thereafter over a 24-month period so that the option was vested and exercisable with respect to 50% of the total number of shares of stock underlying the option on the second anniversary of the First Vesting Date, and (2) 25% of the underlying shares vested upon the Second Vesting Date (e.g., the enrollment of the first patient in the second Qualifying Trial), which occurred as a result of the randomization and first dosing of the first fispemifene patient in May 2015; 1/96th of the total number of shares subject to the option vested monthly thereafter over a 24-month period so that the option was vested and exercisable with respect to 100% of the total number of shares of stock underlying the option on the second anniversary of the Second Vesting Date.

4. Includes performance-based restricted stock units granted in April 2016 (with respect to Mr. Pascoe) and May 2016 (with respect to Messrs. Dorsey and Morton) that will vest upon our receipt of marketing approval of Vitaros in the United States by the FDA on or before December 31, 2018, subject to the executive's continuous employment or service with us through the vesting date, as follows: Mr. Pascoe, 17,500 restricted stock units; Mr. Dorsey, 12,500 restricted stock units; and Mr. Morton, 5,000 restricted stock units.

Also includes performance-based restricted stock units granted in January 2017 and June 2017 that will also vest upon our receipt of marketing approval of Vitaros in the United States by the FDA, subject to the executive's continuous employment or service with us through the vesting date, as follows: Mr. Pascoe, 100,000 restricted stock units; Mr. Dorsey, 75,000 restricted stock units; and Mr. Morton, 75,000 restricted stock units.

In addition, all of these restricted stock units will vest in the event of a "covered transaction" (as defined in the 2012 Plan). The vesting of all of Mr. Dorsey's restricted stock units accelerated upon his termination of employment on August 30, 2018, pursuant to the terms of his release agreement.

5. Computed by multiplying the number of shares underlying each RSU by $0.19202, the closing market price of our common stock on December 31, 2018, the last trading day of 2018.

Payments Upon Termination or Change In Control

We have entered into employment agreements with each of the Named Executive Officers. These agreements set forth the individual's base salary, annual incentive opportunities, equity compensation and other employee benefits, which are described in this Executive Compensation section. All employment agreements provide for "at-will" employment, meaning that either party can terminate the employment relationship at any time, although our agreements with our Named Executive Officers provide that they would be eligible for severance benefits in certain circumstances following a termination of employment without cause. Our Compensation Committee approved the severance benefits to mitigate certain risks associated with working in a biopharmaceutical company at our current stage of development and to help attract and retain qualified executives.

Richard W. Pascoe

On March 18, 2013, we entered into an employment agreement with Richard W. Pascoe when he became our Chief Executive Officer (the "Initial Employment Agreement"). Subsequently, on December 20, 2016, we entered into an amended and restated employment agreement with Mr. Pascoe (the "2016 Employment Agreement"), which superseded and replaced the initial employment agreement.

The 2016 Employment Agreement provided that if Mr. Pascoe's employment ends due to an involuntary termination, as such term is defined in the 2016 Employment Agreement, he would receive, in a lump sum payment, 12 months of his annual base salary in effect on the date of termination, any accrued but unpaid bonus for the calendar year preceding his termination, to the extent that the criteria for the bonus had been met, plus his target bonus for the year in which the date of his involuntary termination occurred, full acceleration and vesting of his unvested equity awards, and reimbursement for the cost of continuation of health insurance benefits provided to him immediately prior to the termination (as provided under Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA") or other applicable law) until the earliest of 12 months following the termination, the date Mr. Pascoe becomes eligible for coverage under health and/or dental plans of another employer or the date upon which he is no longer eligible for such COBRA or other benefits under applicable law.

The 2016 Employment Agreement also provided that if Mr. Pascoe's employment was terminated in connection with his death or a permanent disability, Mr. Pascoe or his estate would have been entitled to a pro rata bonus for the calendar year in which such termination occurred, equal to the bonus he would have received, to the extent all criteria for such a bonus have been met (with the exception of the requirement that he be employed on the date the bonus is to be paid), for the calendar year of termination multiplied by a fraction, the numerator of which is the number of days in such year preceding and including the date of termination, and the denominator of which is 365. Such pro-rata bonus would have been paid at the same time as the bonus would have been paid had Mr. Pascoe remained employed by us through the date of payment, but in any event, not later than March 15 of the calendar year following the calendar year for which the bonus was payable. Mr. Pascoe was also entitled to receive any unpaid bonus for the calendar year preceding his termination, to the extent that all criteria for such bonus had been met (with the exception of the requirement that he be employed on the date the bonus was to be paid). Such bonus would have been paid at the same time as the bonus would have been paid had he remained employed by us through the date of payment. Additionally, all of his outstanding but unvested equity awards would have vested immediately and the expiration date for all such equity awards would have been extended so that they expire one year after termination due to death or permanent disability.

Under the 2016 Employment Agreement, in the event that Mr. Pascoe suffered an involuntary termination within the 12-month period following the effective date of a change of control, then in addition to all salary and bonuses accrued as of the date of his termination he would also have been entitled to severance benefits. These include (i) we would have paid to Mr. Pascoe in one

lump sum an amount equal to the greater of (A) 18 months of the salary that he was receiving immediately prior to the termination or (B) 18 months of the salary that he was receiving immediately prior to the change of control; (ii) we shall pay to Mr. Pascoe in one lump sum (A) any unpaid bonus for the calendar year preceding his termination, to the extent that all criteria for such bonus had been met (with the exception of the requirement that he be employed on the date the bonus was to be paid), plus (B) 100% of his target bonus for the year in which the date of his involuntary termination occurred; (iii) full acceleration of the vesting of all equity awards held by Mr. Pascoe at the time of the termination, including any options, restricted stock, RSUs or other awards, and (iv) reimbursement for the cost of continuation of health insurance benefits provided to him immediately prior to the termination pursuant to the terms of COBRA or other applicable law for a period continuing until the earlier of 18 months following the termination or the date upon which he is no longer eligible for such COBRA or other benefits under applicable law. In addition, Mr. Pascoe's outstanding performance-based stock options as well as the unvested portion of restricted stock units granted in March 2016, April 2016, January 2017, and June 2017 would have vested in the event of a "covered transaction" (as defined in the 2012 Plan).

If he was terminated for cause at any time or resigned under circumstances that did not constitute an involuntary termination, then Mr. Pascoe would not have been entitled to receive payment of any severance benefit or any continuation or acceleration of stock option vesting. He would have received payment for all salary accrued as of the date of termination of employment.

In connection with the merger, the Apricus board of directors approved, and Apricus entered into, an amended and restated employment agreement with Mr. Pascoe dated August 30, 2018 (the "2018 Employment Agreement"). Under the 2018 Employment Agreement, Apricus and Mr. Pascoe agreed as follows:

- Mr. Pascoe's employment will be involuntarily terminated by Apricus effective at the closing of the merger and Mr. Pascoe will be entitled to receive the severance payments described above for an involuntary termination within 12 months following a change of control as a result of such termination.

- In the event the payment of the cash severance to Mr. Pascoe consisting of 18 months of his base salary and his target annual bonus (the "Base and Bonus Severance Obligation") in cash (and assuming that all other Apricus employees are terminated at the closing of the merger and become entitled to severance pursuant to their employment arrangements) would cause the "Apricus Net Cash" (as defined in the Merger Agreement) to be less than $0, then Mr. Pascoe's severance shall be paid as follows:

- Such portion of the Base and Bonus Severance Obligation payable to Mr. Pascoe under his employment agreement as would cause the Apricus Net Cash to be less than $0 (but in no event more than 40% of the Base and Bonus Severance Obligation) (the "Equity-Settled Severance Portion") shall be paid as follows:

- At the closing of the merger, Mr. Pascoe will be granted a restricted stock unit under the Restated Plan (as described in Proposal No. 5), or if the Restated Plan has not yet been approved, under the 2012 Plan, denominated with a dollar value equal to 120% of the Equity-Settled Severance Portion (the "Pascoe Closing RSU").

- The Pascoe Closing RSU will vest in two equal installments on each of March 1, 2019 and March 1, 2020, subject to Mr. Pascoe's continued service to Apricus as director on the applicable vesting date, subject to accelerated vesting in the event of (1) a change of control of Apricus (following the closing of the merger), (2) the failure of the Apricus board of directors to nominate Mr. Pascoe for reelection to the Apricus board of directors or Mr. Pascoe's failure to be reelected to Apricus board of directors at any meeting of Apricus stockholders or any other involuntary termination of Mr. Pascoe's service as a member of the Apricus board of directors of Apricus, or (3) Mr. Pascoe's death or disability.

- The Pascoe Closing RSU will provide for settlement within 10 days of vesting in either (1) shares of the our common stock with an aggregate value equal to the denominated dollar value vesting on the applicable vesting date (which value shall be converted into Apricus shares based on the average closing price of the our common stock over the 20 trading days preceding the settlement date) or (2) in the event any shares cannot be issued under the terms of the Restated Plan or the 2012 Plan, as applicable, for any reason, including as a result of there being insufficient shares available for issuance thereunder or the issuance of shares causing any individual award limit under the plan to be exceeded, in cash with respect to such shares. In addition, Apricus may elect to settle the Pascoe Closing RSU in cash, in its discretion. If the settlement of the Pascoe Closing RSU would not be possible as of the grant date as a result of there being insufficient shares available for issuance under the Restated Plan or the 2012 Plan, as applicable, or the issuance of such shares causing the award to exceed any individual award limits contained in the 2012 Plan, the Pascoe Closing RSU will still be granted but any share settlement shall be subject to the approval by the Apricus board of directors and/or the Apricus stockholders of an amendment to the Restated Plan or the 2012 Plan, as applicable, permitting such share settlement under the terms of such plan (and increasing or deleting the individual award limits).

- The Pascoe Closing RSU will permit Mr. Pascoe to elect net settlement of such RSU for tax withholding purposes.

- Mr. Pascoe shall be entitled to implement a 10b5-1 trading plan with respect to the payment of tax withholding upon settlement of the Pascoe Closing RSU.

- In the event the Pascoe Closing RSU cannot be granted at the closing of the merger under the terms of the Restated Plan or the 2012 Plan for any reason, all of the Base and Bonus Severance Obligations shall instead be paid in cash at the time set forth in the employment agreement.

- The remainder of the Base and Bonus Severance Obligation shall be paid in cash at the time set forth in the employment agreement.

For the avoidance of doubt, the Pascoe Closing RSU would be granted in consideration of Mr. Pascoe's services to Apricus as an employee and not for his services as a non-employee director.

All other terms of the 2016 Employment Agreement remain substantially unchanged. Mr. Pascoe's employment was terminated on January 24, 2019 in connection with the closing of the merger.

Brian T. Dorsey

Employment Agreement with Mr. Dorsey

On December 1, 2014, we entered into an employment agreement with Brian T. Dorsey. Subsequently, on December 20, 2016, we entered into an amended and restated employment agreement with Mr. Dorsey, which superseded and replaced the initial employment agreement. Mr. Dorsey's employment was terminated on August 30, 2018, and he executed a release agreement in connection with such termination, which superseded the employment agreement at that time.

The amended and restated agreement provided that if Mr. Dorsey's employment ended due to an involuntary termination, as such term is defined in his agreement, he would receive, in a lump sum payment, 12 months of his annual base salary in effect on the date of termination, any accrued but unpaid bonus for the calendar year preceding his termination, to the extent that the criteria for the bonus had been met, plus his target bonus for the year in which the date of his involuntary termination occurred, full acceleration and vesting of his unvested equity awards, and reimbursement for the cost of continuation of health insurance benefits provided to him immediately prior to the termination (as provided under COBRA or other applicable law) until the earliest of 12 months following the termination, the date Mr. Dorsey becomes eligible for coverage under health and/or dental plans of another employer or the date upon which he is no longer eligible for such COBRA or other benefits under applicable law.

If Mr. Dorsey's employment was terminated in connection with his death or a permanent disability, Mr. Dorsey or his estate was entitled to a pro rata target bonus for the calendar year in which such termination occurred. Mr. Dorsey was also entitled to receive any accrued but unpaid bonus for the calendar year preceding his termination, to the extent that all criteria for such bonus have been met (with the exception of the requirement that he be employed on the date the bonus is to be paid). Such bonus amounts would be paid in cash in a lump sum following the effectiveness of a general release of claims (or, in the event of his death, within five days following the date of death). Additionally, all of his outstanding but unvested equity awards would vest immediately and the expiration date for all such equity awards would be extended so that they expire one year after termination due to death or permanent disability.

In the event that Mr. Dorsey suffered an involuntary termination within the 12-month period following the effective date of a change of control, then in addition to all salary accrued as of the date of his termination he will also be entitled to severance benefits. These include (i) we would pay to Mr. Dorsey in one lump sum an amount equal to the greater of (A) 18 months of the salary that he was receiving immediately prior to the termination or (B) 18 months of the salary that he was receiving immediately prior to the change of control; (ii) we shall pay to Mr. Dorsey in one lump sum (A) any accrued but unpaid bonus for the calendar year preceding his termination, to the extent that all criteria for such bonus have been met (with the exception of the requirement that he be employed on the date the bonus is to be paid), plus (B) 100% of his target bonus for the year in which the date of his involuntary termination occurred; (iii) full acceleration of the vesting of all equity awards held by Mr. Dorsey at the time of the termination, including any options, restricted stock, RSUs or other awards, and (iv) reimbursement for the cost of continuation of health insurance benefits provided to him immediately prior to the termination pursuant to the terms of COBRA or other applicable law for a period continuing until the earlier of 18 months following the termination or the date upon which he is no longer eligible for such COBRA or other benefits under applicable law. In addition, Mr. Dorsey's outstanding performance-based stock options as well as the unvested portion of restricted stock units granted in March 2016, May 2016, January 2017, and June 2017 will vest in the event of a "covered transaction" (as defined in the 2012 Plan).

If he was terminated for cause at any time or if he voluntarily resigned under circumstances that did not constitute an involuntary termination, then Mr. Dorsey would not be entitled to receive payment of any severance benefit or any continuation or acceleration of stock option vesting and all of his restricted stock awards shall remain subject to all applicable forfeiture provisions and transfer restrictions. He would receive payment for all salary accrued as of the date of termination of employment.

Consulting Agreement and Release Agreement with Mr. Dorsey

On August 30, 2018, Mr. Dorsey's employment with Apricus terminated and Apricus entered into a consulting agreement with Mr. Dorsey pursuant to which he will consult with Apricus on an as-needed basis through March 31, 2019, and assist with any transition of the Vitaros assets to an interested third party in conjunction with its sale or license. In connection with his termination of employment, the Apricus board of directors approved, and Apricus entered into, a release agreement with Mr. Dorsey dated August 30, 2018. Under the release agreement, Apricus and Mr. Dorsey agreed as follows:

- Mr. Dorsey will receive a cash payment in the amount of $447,020, representing 12 months of his annual base salary in effect on the date of his termination plus his target bonus for 2018, payable in a lump sum within five days following the effective date of the release agreement.

- All of Mr. Dorsey's outstanding equity awards vested in full effective as of the date of his termination of employment.

- Mr. Dorsey will be reimbursed for the cost of continuation of health insurance benefits provided to him immediately prior to the termination (as provided under COBRA or other applicable law) until the earliest of 12 months following the date of his termination of employment, the date Mr. Dorsey becomes eligible for coverage under health and/or dental plans of another employer or the date upon which he is no longer eligible for such COBRA or other benefits under applicable law.

- In addition, in the event the merger closes on or before March 5, 2019, Mr. Dorsey will be eligible to receive, at the closing of the merger, a restricted stock unit under the Restated Plan (as described in Proposal No. 5), or if the Restated Plan has not yet been approved, under the 2012 Plan, denominated with a dollar value equal to $159,650 (the "Dorsey Closing RSU").

- The Dorsey Closing RSU will vest on March 5, 2019, subject to Mr. Dorsey's continued service to Apricus as a consultant on such date, subject to accelerated vesting in the event of (1) a change of control of Apricus (following the closing of the merger), or (2) the termination of Mr. Dorsey's consulting services with Apricus for any reason other than his voluntary termination of such services, or (3) Mr. Dorsey's death or disability.

- The Dorsey Closing RSU will provide for settlement within 10 days of vesting in either (1) shares of our common stock with an aggregate value equal to the denominated dollar value vesting on the applicable vesting date (which value shall be converted into shares of our common stock based on the average closing price of our common stock over the 20 trading days preceding the settlement date) or (2) in the event any shares cannot be issued under the terms of the Restated Plan or the 2012 Plan, as applicable, for any reason, including as a result of there being insufficient shares available for issuance thereunder or the issuance of shares causing any individual award limit under the plan to be exceeded, in cash with respect to such shares. In addition, Apricus may elect to settle the Dorsey Closing RSU in cash, in its discretion. If the settlement of the Dorsey Closing RSU would not be possible as of the grant date as a result of there being insufficient shares available for issuance under the Restated Plan or the 2012 Plan, as applicable, or the issuance of such shares causing the award to exceed any individual award limits contained in the 2012 Plan, the Dorsey Closing RSU will still be granted but any share settlement shall be subject to the approval by the Apricus board and/or the Apricus stockholders of an amendment to the Restated Plan or the 2012 Plan, as applicable, permitting such share settlement under the terms of such plan (and increasing or deleting the individual award limits).

- The Dorsey Closing RSU will permit Mr. Dorsey to elect net settlement of such RSU for tax withholding purposes.

- Mr. Dorsey shall be entitled to implement a 10b5-1 trading plan with respect to the payment of tax withholding upon settlement of the Dorsey Closing RSU.

The value of the Dorsey Closing RSU was paid to Mr. Dorsey on January 24, 2019 in connection with the closing of the merger.

Neil Morton

On March 20, 2014, we entered into an employment agreement with Neil Morton, which was later amended and restated on April 25, 2016. Subsequently, on December 20, 2016, we entered into a second amended and restated employment agreement with Mr. Morton, which superseded and replaced the first amended and restated employment agreement. Mr. Morton's employment was terminated on January 24, 2019 in connection with the closing of the merger.

The second amended and restated agreement provided that if Mr. Morton's employment ended due to an involuntary termination, as such term is defined in his agreement, he would receive, in a lump sum payment, 12 months of his annual base salary in effect on the date of termination, any accrued but unpaid bonus for the calendar year preceding his termination, to the extent that the criteria for the bonus had been met, plus his target bonus for the year in which the date of his involuntary termination occurred, full acceleration and vesting of his unvested equity awards, and reimbursement for the cost of continuation of health insurance benefits provided to him immediately prior to the termination (as provided under COBRA or other applicable law) until the earliest of 12 months following the termination, the date Mr. Morton becomes eligible for coverage under health and/or dental plans of another employer or the date upon which he is no longer eligible for such COBRA or other benefits under applicable law.

If Mr. Morton's employment was terminated in connection with his death or a permanent disability, Mr. Morton or his estate was entitled to a pro rata target bonus for the calendar year in which such termination occurred. Mr. Morton was also entitled to receive any accrued but unpaid bonus for the calendar year preceding his termination, to the extent that all criteria for such bonus have been met (with the exception of the requirement that he be employed on the date the bonus is to be paid). Such bonus amounts would be paid in cash in a lump sum following the effectiveness of a general release of claims (or, in the event of his death, within five days following the date of death). Additionally, all of his outstanding but unvested equity awards would vest immediately and the expiration date for all such equity awards would be extended so that they expire one year after termination due to death or permanent disability.

In the event that Mr. Morton suffered an involuntary termination within the 12-month period following the effective date of a change of control, then in addition to all salary accrued as of the date of his termination he would also be entitled to severance benefits. These include (i) we would pay to Mr. Morton in one lump sum an amount equal to the greater of (A) 18 months of the salary that he was receiving immediately prior to the termination or (B) 18 months of the salary that he was receiving immediately prior to the change of control; (ii) we would pay to Mr. Morton in one lump sum (A) any accrued but unpaid bonus for the calendar year preceding his termination, to the extent that all criteria for such bonus have been met (with the exception of the requirement that he be employed on the date the bonus is to be paid), plus (B) 100% of his target bonus for the year in which the date of his involuntary termination occurred; (iii) full acceleration of the vesting of all equity awards held by Mr. Morton at the time of the termination, including any options, restricted stock, RSUs or other awards, and (iv) reimbursement for the cost of continuation of health insurance benefits provided to him immediately prior to the termination pursuant to the terms of COBRA or other applicable law for a period continuing until the earlier of 18 months following the termination or the date upon which he is no longer eligible for such COBRA or other benefits under applicable law. In addition, Mr. Morton's outstanding performance-based stock options as well as the unvested portion of restricted stock units granted in March 2016, May 2016, January 2017, and June 2017 will vest in the event of a "covered transaction" (as defined in the 2012 Plan).

If he was terminated for cause at any time or if he voluntarily resigned under circumstances that did not constitute an involuntary termination, then Mr. Morton would not be entitled to receive payment of any severance benefit or any continuation or acceleration of stock option vesting and all of his restricted stock awards shall remain subject to all applicable forfeiture provisions and transfer restrictions. He would receive payment for all salary accrued as of the date of termination of employment.

DIRECTOR COMPENSATION

We have adopted a non-employee director compensation policy pursuant to which our non-employee directors are eligible to receive cash and equity compensation.

Each non-employee director is entitled to receive an annual cash retainer of $40,000, with additional annual cash retainers for the chairs of our various Board committees in the following amounts: $15,000 for the chair of the Audit Committee, $12,000 for the chair of the Compensation Committee and $8,000 for the chair of the Corporate Governance/Nominating Committee. Additionally, non-chair members of these committees will receive additional annual cash retainers in the following amounts: $7,000 for members of the Audit Committee, $5,000 for members of the Compensation Committee and $3,000 for members of the Corporate Governance/Nominating Committee. The Chairman of the Board is also entitled to receive an additional annual cash retainer of $40,000 per year.

Prior to March 20, 2019, each non-employee director was eligible to receive a non-qualified stock option to purchase 60,000 shares of our common stock upon initial election or appointment to the Board, subject to the terms and provisions of the 2012 Plan. Such initial awards vest over four years, with one-fourth of the shares subject to the initial award vesting on the first anniversary of the date of grant and the remaining shares subject to the initial award vesting in 36 equal monthly installments over the three years thereafter, subject to the director's continuing service on our Board through such dates.

Prior to January 3, 2018, on the third trading day of each calendar year, each non-employee director was eligible to receive an annual grant of 11,250 restricted stock units (or, in the case of our Chairman of the Board, 15,000 restricted stock units), subject to the terms and provisions of the 2012 Plan. Such restricted stock units vested upon the first anniversary of the date of grant, subject to the director's continuing service on our Board on such date.

On January 3, 2018, our Board approved an amendment to the equity component of our non-employee director compensation policy such that the annual grant of equity would be in the form of options rather than restricted stock units. As such, pursuant to the amendment, prior to March 20, 2019, on the third trading day of each calendar year, each non-employee director was eligible to receive a non-qualified stock option to purchase 35,000 shares of our common stock (or, in the case of our Chairman of the Board, an option to purchase 50,000 shares of Common Stock), subject to the terms and provisions of the 2012 Plan.

On January 3, 2019, our Board determined to suspend our non-employee director compensation policy in light of the pending closing of the Merger.

On March 20, 2019, our Compensation Committee adopted a new non-employee director compensation policy, which amended the equity component of our non-employee director compensation policy, such that each non-employee director is eligible to receive a non-qualified stock option to purchase 24,000 shares of our common stock upon initial election or appointment to the Board, subject to the terms and provisions of the 2012 Plan, provided that the directors appointed in connection with the Merger were granted such award on March 20, 2019. Such initial awards vest over three years, with one-third of the shares subject to the initial award vesting on the first anniversary of the date of grant and the remaining shares subject to the initial award vesting in 24 equal monthly installments over the two years thereafter, subject to the director's continuing service on our Board through such dates,

The new non-employee director compensation policy also amended the equity component of our non-employee director compensation policy, such that on the third trading day of each calendar year, each non-employee director is eligible to receive a non-qualified stock option to purchase 16,000 shares of our common stock, subject to the terms and provisions of the 2012 Plan, provided that the directors appointed in connection with the Merger were granted such award on March 20, 2019. Annual awards vest over one year in 12 equal monthly installments, subject to the director's continuing service on our Board through such dates. All initial and annual awards to our non-employee directors will vest in full in the event of a change in control

Non-Employee Director Compensation for 2018

Below is a summary of the non-employee director compensation paid in fiscal 2018:

Name	Cash Compensation (1)	Option Grants (2)	Stock Awards (3)	Total
Kleanthis G. Xanthopoulos, Ph.D.	$ 92,000	$ 96,710	$ -	$ 188,710
Russell Ray	$ 55,000	$ 67,697	$ -	$ 122,697
Paul V. Maier	$ 58,000	$ 67,697	$ -	$ 125,697
Wendell Wierenga, Ph.D.	$ 48,000	$ 67,697	$ -	$ 115,697
Sandford D. Smith	$ 52,000	$ 67,697	$ -	$ 119,697

1. Includes the value of the annual retainers payable to our non-employee directors.

2. Represents the grant date fair value of the stock options granted in 2018, computed in accordance with FASB ASC Topic 718. As of December 31, 2018, each of our non-employee directors held stock options to purchase the following number of shares of our Common Stock: Dr. Xanthopoulos, options to purchase 64,034 shares; Mr. Ray, options to purchase 42,784 shares; Mr. Maier, options to purchase 43,684 shares; Dr. Wierenga, options to purchase 47,084 shares; and Mr. Smith, options to purchase 45,584 shares.

3. No stock awards were granted to the directors in 2018.

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

The following table sets forth information with respect to the beneficial ownership, as of January 31, 2019 (the "Reference Date"), of our common stock by (a) each of our Named Executive Officers and current directors individually, (b) our current directors and executive officers as a group and (c) each holder of more than 5% of our outstanding common stock.

Beneficial ownership and percentage ownership are determined in accordance with the Rule 13d-3 of the Exchange Act. Under these rules, shares of our common stock issuable under stock options or warrants that are exercisable within 60 days of the Reference Date are deemed outstanding for the purpose of computing the percentage ownership of the person holding the options or warrant(s), but are not deemed outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated and subject to applicable community property laws, to our knowledge, each stockholder named in the following table possesses sole voting and investment power over their shares of our common stock, except for those jointly owned with that person's spouse.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Class (%) (1)
Raj Mehra, Ph.D. (2)	3,081,546	49.50%
Hudson Bay Master Fund Ltd. (3)	470,396	7.28%
Altium Growth Fund, LP (4)	411,616	6.43%
Entities Affiliated with Empery Asset Management LP (5)	411,612	6.43%
CVI Investments, Inc. (6)	411,616	6.43%
Directors and Executive Officers (7)		
Richard W. Pascoe, Director (8)	19,071	*
Brian T. Dorsey, Former Senior Vice President, Chief Development Officer (9)	7,530	*
Neil Morton, Former Senior Vice President, Chief Business Officer (10)	7,038	*
Robin L. Smith M.D., Director	-	*
Daniel J. O'Connor, Director	-	*
Brian Lian Ph.D., Director	-	*
All current executive officers and directors as a group (five persons) (11)	3,100,617	49.70%

* Less than one percent.

(1) Percentage ownership is calculated based on a total of 6,221,984 shares of our common stock issued and outstanding as of the Reference Date.

(2) Represents 3,081,546 shares of our common stock held by Raj Mehra, Ph.D.

(3) Represents (i) 226,475 shares of our common stock held directly by Hudson Bay Master Fund Ltd. and (ii) 243,921 shares of our common stock issuable upon exercise of warrants. Hudson Bay Capital Management, L.P., the investment manager of Hudson Bay Master Fund Ltd., has voting and investment power over these securities. Sander Gerber is the managing member of Hudson Bay Capital GP LLC, which is the general partner of Hudson Bay Capital Management, L.P. Each of Hudson Bay Master Fund Ltd. and Sander Gerber disclaims beneficial ownership over these securities.

(4) Represents (i) 228,676 shares of our common stock hares held directly by Altium Growth Fund, LP and (ii) 182,940 shares of our common stock issuable upon exercise of warrants. Altium Capital Management, LP, the investment manager of Altium Growth Fund, LP, has voting and investment power over these securities. Jacob Gottlieb is the managing member of Altium Capital Growth GP, LLC, which is the general partner of Altium Growth Fund, LP. Each of Altium Growth Fund, LP and Jacob Gottlieb disclaims beneficial ownership over these securities.

(5) Represents (i) 105,142 shares of our common stock held directly by Empery Asset Master, Ltd. ("EAM"), (ii) 84,113 shares of our common stock issuable upon exercise of warrants held by EAM, (iii) 16,710 shares of our common stock held directly by Empery Tax Efficient, LP ("ETE"), (iv) 13,368 shares of our common stock issuable upon exercise of warrants held by ETE, (v) 106,823 shares of our common stock held directly by Empery Tax Efficient II, LP ("ETE II") and (vi) 85,457 shares of our common stock issuable upon exercise of warrants held by ETE II. Empery Asset Management LP, the authorized agent of EAM, ETE and ETE II has discretionary authority to vote and dispose of the shares held by EAM, ETE and ETE II and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by EAM, ETE and ETE II. EAM, ETE, ETE II, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares.

(6) Represents (i) 228,676 shares of our common stock held directly by CVI Investments, Inc. ("CVI") and (ii) 1,372,055 shares of our common stock issuable upon exercise of warrants. Heights Capital Management, Inc., the authorized agent of CVI has discretionary authority to vote and dispose of the shares held by CVI and may be deemed to be the beneficial owner of these shares. Martin Kobinger, in his capacity as Investment Manager of Heights Capital Management, Inc., may also be deemed to have investment discretion and voting power over the shares held by CVI. Mr. Kobinger disclaims any such beneficial ownership of the shares. The address for CVI Investments, Inc. is c/o Heights Capital Management, Inc., 101 California Street, Suite 3250, San Francisco, California 94111. CVI is affiliated with one or more FINRA members. CVI purchased the shares being registered hereunder in the ordinary course of business and at the time of purchase, had no agreements or understandings, directly or indirectly, with any other person to distribute such shares.

(7) Unless otherwise indicated, the address for each of our executive officers and directors is c/o 300 Park Avenue, 12th Floor, New York, NY 10022.

(8) Represents (i) 5,180 shares of our common stock held directly by Richard Pascoe, (ii) 59 shares of our common stock issuable upon exercise of warrants and (iii) 13,832 shares of our common stock issuable upon exercise of stock options.

(9) Represents (i) 3,864 shares of our common stock held directly by Brian T. Dorsey and (ii) 3,666 shares of our common stock issuable upon exercise of stock options. Mr. Dorsey's employment was terminated on August 30, 2018.

(10) Represents (i) 3,339 shares of our common stock held directly by Neil Morton and (ii) 3,699 shares of our common stock issuable upon exercise of stock options. Mr. Morton's employment was terminated on January 24, 2019.

(11) Comprised of shares beneficially owned by each of our directors, including Dr. Mehra, our Chairman, Chief Executive Officer, President & Interim Chief Financial Officer.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Described below are any transactions occurring since January 1, 2018 and any currently proposed transactions to which we were a party and in which:

- the amounts involved exceeded or will exceed $120,000; and
- a director, executive officer, holder of more than 5% of the outstanding capital stock of Seelos or STI, or any member of such person's immediate family had or will have a direct or indirect material interest.

Transactions with Related Persons

IRRAS AB ("IRRAS") is a commercial stage medical technology company of which a former director of Seelos, Kleanthis G. Xanthopoulos, Ph.D., is currently the President, Chief Executive Officer and director. In January 2018, Seelos and IRRAS entered into a Sublease, pursuant to which Seelos subleased to IRRAS excess capacity in its corporate headquarters. The sublease has a term of two years and aggregate payments due to Seelos of approximately $0.3 million. On October 30, 2018, Seelos and IRRAS entered into an amended and restated sublease, commencing January 1, 2019, pursuant to which Seelos agreed to sublease to IRRAS the remainder of its current corporate headquarters (the "IRRAS Restated Sublease"), which satisfied a closing condition related to the Merger. The IRRAS Sublease has a term of one year and provides for aggregate payments due to Seelos of approximately $0.4 million, which approximate fair value.

The employment and release agreements Seelos entered into with each of its former executive officers provide for severance benefits in specified circumstances, as well as benefits in connection with a change in control. See "*Executive Compensation - Payments Upon Termination or Change In Control*" for additional information about these arrangements.

Dr. Raj Mehra is an executive officer of each of Seelos and STI, a member of each of Seelos' and STI's respective boards of directors and, in his individual capacity, a holder of more than 5% of Seelos' outstanding capital stock. Prior to the Merger, Dr. Mehra was also a holder of more than 5% of STI's outstanding capital stock. Dr. Mehra received 3,081,546 shares of our common stock in the Merger.

In connection with the Merger and in accordance with the terms of the Merger Agreement, STI also entered into a Support Agreement, with Dr. Mehra, pursuant to which, among other things Dr. Mehra agreed, solely in his capacity as a stockholder of STI, to vote all of his shares of STI's common stock in favor of the adoption of the Merger Agreement and the approval of the Merger and against any action or agreement that would reasonably be expected to result in a material breach of any covenant, representation, warranty or other obligation of STI under the Merger Agreement. He also agreed to vote against any acquisition proposal or other matter that would reasonably be expected to impede, interfere with, delay, postpone, discourage or materially adversely affect the consummation of the Merger and the transactions contemplated by the Merger Agreement. Dr. Mehra also granted STI an irrevocable proxy to vote his STI common stock in accordance with the support agreement.

Our Fourth Amended and Restated Bylaws, as amended, provide that we will indemnify each of our directors and officers to the fullest extent permitted by the laws of the State of Nevada, subject to certain limitations. Further, we have purchased a policy of directors' and officers' liability insurance that insures directors and officers against the cost of defense, settlement or payment of a judgment under certain circumstances.

Director Independence

Our Board has determined that each of Drs. Lian and Smith and Mr. O'Connor met the definitions of independence under the Nasdaq Marketplace Rules and Section 10A-3 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Accordingly, all of our directors, other than our Chief Executive Officer, Dr. Mehra, and our former Chief Executive Officer, Mr. Pascoe, are deemed to be independent.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Fees for Independent Registered Public Accounting Firm

The following is a summary of the fees billed to us by BDO for professional services rendered for the fiscal years ended December 31, 2018 and 2017, respectively:

	2018	2017
Audit Fees [1]	$ 394,789	$ 349,284
Tax Fees [2]	21,500	101,300
Total All Fees	$ 416,289	$ 450,584

(1) Audit fees consist of estimated fees for professional services performed by BDO USA, LLP for the audit of our annual financial statements that will be included in our Form 10-K filing and review of financial statements included in our quarterly Form 10-Q filings, reviews of registration statements and issuances of consents, comfort letters and services that are normally provided in connection with statutory and regulatory filings or engagements.

(2) Consists of fees billed for tax compliance and consulting.

Pre-Approval Policies and Procedures

All audit and non-audit services provided by BDO must be pre-approved by the Audit Committee. BDO will provide the Audit Committee with an engagement letter during the first half of the fiscal year, outlining the scope of the proposed services and estimated fees for the fiscal year. Pre-approval may be given for a category of services, provided that (i) the category is reasonably narrow and detailed and (ii) the Audit Committee establishes a fee limit for such category. The Audit Committee may delegate to any other member of the Audit Committee the authority to grant pre-approval of permitted non-audit services to be provided by BDO between Audit Committee meetings; provided, however, that any such pre-approval shall be presented to the full Audit Committee at its next scheduled meeting. The Audit Committee pre-approved all audit and permitted non-audit services provided by BDO in fiscal 2018 and 2017.

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, 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 Registration Statement on Form 8-K filed with the Securities and Exchange Commission on July 30, 2018).
2.2	Form of Support Agreement, by and between the Company, Seelos Therapeutics, Inc. and certain stockholders of the Company (incorporated by reference to Exhibit 2.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 30, 2018).
2.3	Support Agreement, dated July 30, 2018, by and between the Company, Seelos Therapeutics, Inc. and Raj Mehra (incorporated by reference to Exhibit 2.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 30, 2018).
2.4	Form of Voting Agreement (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 September 21, 2018).
2.5	Amendment No. 1 to Agreement and Plan of Merger, 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).
2.6	Amendment No. 2 to Agreement and Plan of Merger, 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).
2.7	Amendment No. 3 to Agreement and Plan of Merger, 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).
2.8†	Stock Purchase Agreement, dated December 15, 2011, by and among the Company's, TopoTarget A/S, and TopoTarget USA, Inc. (incorporated herein by reference to Exhibit 2.1 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 13, 2012).
2.9	Stock Contribution Agreement, dated June 19, 2012, by and among the Company's, Finesco SAS, Scomedica SA and the shareholders of Finesco named therein (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report Form 8-K filed with the Securities and Exchange Commission on July 13, 2012).
2.10†	Asset Purchase Agreement by and between Apricus Pharmaceuticals USA, Inc. and Biocodex, Inc., dated March 26, 2013 (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 April 1, 2013).
2.11	Amendment to Stock Purchase Agreement, dated June 13, 2014, by and between the Company and Samm Solutions, Inc. (doing business as BTS Research and formerly doing business as BioTox Sciences) (incorporated herein by reference to Exhibit 2.1 to the Company's Form 10-Q filed with Securities and Exchange Commission on August 11, 2014).

2.12*	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 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 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-A12GK 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 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 Registrant'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 Registrant'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 Registrant'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 Registrant'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 (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on From 8-K filed with the Securities and Exchange Commission on May 24, 2013).
4.3	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 Form 8-K filed with the Securities and Exchange Commission on October 20, 2014).
4.4	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).
4.5	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).
4.6	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).
4.7	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).
4.8	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).
4.9	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).
4.10	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).

4.11	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).
4.12	Form of Indenture (incorporated herein by reference to Exhibit 4.13 to the Company's Form S-3 (File No. 333-221285) filed with the Securities and Exchange Commission on November 2, 2017).
4.13	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).
4.14	Amendment to Warrant to Purchase Common Stock, dated as of March 27, 2018 (incorporated by reference to Exhibit 4.1 to the Company's 8-K filed with the Securities and Exchange Commission on March 29, 2018).
4.15	Form of Warrant (incorporated by reference to Exhibit 4.2 to the Company's 8-K filed with the Securities and Exchange Commission on March 29, 2018).
4.16	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.3 to the Company's 8-K filed with the Securities and Exchange Commission on March 29, 2018).
4.17	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 8-K filed with the Securities and Exchange Commission on June 22, 2018).
4.18	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).
4.19	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).
4.20	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).
4.21	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).
4.22	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).
4.23	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).
4.24	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).

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	Asset Purchase Agreement, dated February 3, 2009, by and between Warner Chilcott Company, Inc. and the Company (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 February 5, 2009).
10.4	License Agreement, dated February 3, 2009, by and between the Company and Warner Chilcott Company, Inc. (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 February 5, 2009).
10.5	Settlement Agreement and Release, dated as of September 23, 2013, by and between the Company and Topotarget A/S (incorporated by reference to Exhibit 10.1 of Amendment No. 1 to the Company's Registration Statement on Form S-3 (File No. 333-191679) filed with the Securities and Exchange Commission on October 31, 2013).
10.6#	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).
10.7	Stock Issuance Agreement, by and among the Company, Forendo Pharma Ltd. and Birch & Lake Partners, LLC, dated as of October 17, 2014 (incorporated herein by reference to Exhibit 10.2 to the Company's Form 8-K filed with the Securities and Exchange Commission on October 20, 2014).
10.8†	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 Form 10-Q filed with the Securities and Exchange Commission on November 5, 2015).
10.9	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).
10.10	Employment Transition Agreement, by and between the Company and Dr. Barbara Troupin, dated April 13, 2016 (incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 9, 2016).
10.11#	Form of Restricted Stock Unit Award Agreement (incorporated herein by reference to Exhibit 10.6 to the Company's Form 10-Q filed with the Securities and Exchange Commission on May 9, 2016).

10.12#	Non-Employee Director Compensation Policy (incorporated herein by reference to Exhibit 10.7 to the Company's Form 10-Q filed with the Securities and Exchange Commission on May 9, 2016).
10.13	Form of Securities Purchase Agreement (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 September 28, 2016).
10.14#	Second Amended and Restated Employment Agreement by and between the Company and Richard W. Pascoe, December 20, 2016 (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 30, 2018).
10.15#	Amended and Restated Employment Agreement, by and between the Company and Neil Morton, dated December 20, 2016 (incorporated herein by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 13, 2017).
10.16#	Amended and Restated Employment Agreement by and between the Company and Brian Dorsey, dated December 20, 2016 (incorporated herein by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 13, 2017).
10.17#	Release, by and between the Company and Brian Dorsey, dated August 30, 2018 (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 August 30, 2018).
10.18	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).
10.19	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).
10.20	Transition Services Agreement, dated March 8, 2017, by and between the Company and Ferring International Center S.A. (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 8, 2017).
10.21#	2012 Stock Long Term Incentive Plan, as amended and restated effective May 17, 2017 (incorporated herein by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A filed on April 13, 2017).
10.22	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).
10.23	Securities Purchase Agreement dated as of September 10, 2017, between the Company and each purchaser named in the signature pages 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 September 11, 2017).

10.24	Engagement Letter between the Company and H.C. Wainwright & Co., LLC, dated as of September 10, 2017 (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 September 11, 2017).
10.25	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's 8-K filed with the Securities and Exchange Commission on March 29, 2018).
10.26	Engagement Agreement, dated as of March 27, 2018, between the Company and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 10.2 to the Company's 8-K filed with the Securities and Exchange Commission on March 29, 2018).
10.27	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 8-K filed with the Securities and Exchange Commission on June 22, 2018).
10.28	Form of CVR Agreement (incorporated by reference to Exhibit 10.1 to the Company's 8-K filed with the Securities and Exchange Commission on July 30, 2018).
10.29*	Engagement Letter, between the Company and Canaccord Genuity LLC, dated as of March 22, 2018 (incorporated by reference to Exhibit 10.31 of the Company's Form S-4 filed on August 31, 2018).
10.30	Form of Indemnification Agreement for the Company's Directors and Officers (incorporated by reference to Exhibit 10.32 of the Company's Form S-4 filed on August 31, 2018).
10.31*†	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 Form S-4 filed on August 31, 2018).
10.32*†	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 Form S-4 filed on August 31, 2018).
10.33†	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 Form S-4 filed on August 31, 2018).
10.34	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 Form S-4 filed on August 31, 2018).
10.35	Form of Seelos Therapeutics, Inc. Note Purchase Agreement (incorporated by reference to Exhibit 10.37 of the Company's Form S-4 filed on August 31, 2018).
10.36	Form of Seelos Therapeutics, Inc. Convertible Promissory Note (incorporated by reference to Exhibit 10.38 of the Company's Form S-4 filed on August 31, 2018)..
10.37#	Seelos Therapeutics, Inc. 2016 Equity Incentive Plan (incorporated by reference to Exhibit 10.39 of the Company's Form S-4 filed on August 31, 2018).
10.38#	Form of Option Agreement under the Seelos Therapeutics, Inc. 2016 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 of the Company's Form S-4 filed on August 31, 2018).

10.39	Securities Purchase Agreement, dated as of September 20, 2018, between the Company and the purchaser named in the signature pages 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 September 21, 2018).
10.40	Securities Purchase Agreement, dated as of October 16, 2018, 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 October 17, 2018).
10.41	Conversion Agreement, effective as of October 15, 2018, by and among Seelos Therapeutics, Inc., and the holders listed on the Schedule of Holders attached thereto (incorporated herein by reference to Exhibit 10.43 to the Company's Amendment No. 2 to the Form S-4 filed with the Securities and Exchange Commission on October 24, 2018).
10.42	Form of Escrow Agreement (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 October 17, 2018).
10.43	Form of Lock-Up Agreement (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 17, 2018).
10.44	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).
10.45	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).
10.46#	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).
10.47#	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).
21.1	Subsidiaries.
23.1	Consent of BDO USA, 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.
# Management compensatory plan or arrangement
† Confidential treatment has been requested for portions of this exhibit. Those portions have been omitted and filed separately with 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 28, 2019

/s/ Raj Mehra, Ph.D.

Raj Mehra, Ph.D.

President and Chief Executive Officer

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 28, 2019
/s/ Brian Lian, Ph.D. Brian Lian, Ph.D.	Director	March 28, 2019
/s/ Daniel J. O'Connor, J.D. Daniel J. O'Connor, J.D.	Director	March 28, 2019
/s/ Richard W. Pascoe Richard W. Pascoe	Director	March 28, 2019
/s/ Dr. Robin L. Smith Robin L. Smith	Director	March 28, 2019

EXHIBIT 21.1

SUBSIDIARIES OF SEELOS THERAPEUTICS, INC.

1. NexMed (U.S.A.), Inc., incorporated in Delaware on June 18, 1997.
2. Apricus Pharmaceuticals USA, Inc. (formerly Topotarget USA, Inc.), incorporated in Delaware on July 12, 2006 and acquired by Seelos Therapeutics, Inc. (formerly Apricus Biosciences, Inc.) on December 29, 2011.
3. NexMed Holdings, Inc., incorporated in Delaware on February 28, 1997.
4. NexMed International Limited, incorporated in the British Virgin Islands on August 2, 1996.
5. Seelos Corporation (formerly Seelos Therapeutics, Inc.), incorporated in Delaware on June 1, 2016 and acquired by Seelos Therapeutics, Inc. on January 24, 2019.

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

Seelos Therapeutics, Inc. (formerly Apricus Biosciences, Inc.)

We hereby consent to the incorporation by reference in the Registration Statements on Form S3 (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) and Form S-8 (Nos. 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) of Seelos Therapeutics, Inc. (formerly Apricus Biosciences, Inc.) of our report dated March 28, 2019, relating to the consolidated financial statements, which appears in this Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP
San Diego, California

March 28, 2019

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 28, 2019

/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 of Seelos Therapeutics, Inc. on Form 10-K for the year ended December 31, 2018 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 28, 2019

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

Name: Raj Mehra, Ph.D.

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