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

FORM 10-K

(Mark One)

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

For the fiscal year ended: December 31, 2019

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

For the transition period from ________ to ________ .

Commission File No.: 001-36593

Soleno Therapeutics, Inc.
(Exact name of Registrant as specified in its charter)

Delaware **(State or other Jurisdiction of Incorporation or Organization)**	**77-0523891** **(I.R.S. Employer Identification No.)**
203 Redwood Shores Parkway, Suite 500 **Redwood City, California** **(Address of principal executive offices)**	**94065** **(Zip Code)**

Registrant's telephone number, including area code: (650) 213-8444

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	SLNO	NASDAQ

Securities Registered Pursuant to Section 12(g) of the Act: None.

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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 ☒

The aggregate market value of stock held by non-affiliates of the registrant on June 28, 2019, based on the closing price of $2.80 for shares of the registrant's common stock as reported by the NASDAQ Capital Market, was approximately $28.0 million. Shares of Common Stock held by each executive officer, director and beneficial holder of 5% or more of the outstanding Common Stock have been excluded in that such persons may be deemed affiliates.

As of February 28, 2020 there were 44,686,811 shares of the registrant's Common Stock, par value $0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement to be filed with the Commission pursuant to Regulation 14A in connection with the registrant's 2020 Annual Meeting of Stockholders, to be filed subsequent to the date hereof, are incorporated by reference into Part III of this Report. Such Definitive Proxy Statement will be filed with the Securities and Exchange Commission not later than 120 days after the conclusion of the registrant's fiscal year ended December 31, 2019. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part of this Form 10-K.

Soleno Therapeutics, Inc.
Annual Report on Form 10-K
For the Year Ended December 31, 2019

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

The following discussion and analysis should be read in conjunction with our audited consolidated financial statements and the related notes that appear elsewhere in this Annual Report on Form 10-K. This Annual Report on Form 10-K contains “forward-looking statements” within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, particularly in Part I, Item 1: “Business,” Part I, Item 1A: “Risk Factors” and Part 2, Item 7: “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” These statements are often identified by the use of words such as “may,” “will,” “expect,” “believe,” “anticipate,” “intend,” “could,” “should,” “estimate,” “plan” or “continue,” and similar expressions or variations. All statements other than statements of historical fact could be deemed forward-looking, including, but not limited to: any projections of financial information; any statements about historical results that may suggest trends for our business; any statements of the plans, strategies, and objectives of management for future operations; any statements of expectation or belief regarding future events, technology developments, our products, product sales, the regulatory regime for our products, expenses, liquidity, cash flow, market growth rates or enforceability of our intellectual property rights and related litigation expenses; and any statements of assumptions underlying any of the foregoing. Such forward-looking statements are subject to risks, uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Accordingly, we caution you not to place undue reliance on these statements. Particular uncertainties that could affect future results include: our ability to achieve or maintain profitability; our ability to obtain substantial additional capital that may be necessary to expand our business; our ability to maintain internal control over financial reporting; our dependence on, and need to attract and retain, key management and other personnel; our ability to obtain, protect and enforce our intellectual property rights; potential advantages that our competitors and potential competitors may have in securing funding or developing products; business interruptions such as earthquakes and other natural disasters; our ability to comply with laws and regulations; potential product liability claims; and our ability to use our net operating loss carryforwards to offset future taxable income. For a discussion of some of the factors that could cause actual results to differ materially from our forward-looking statements, see the discussion on risk factors that appear in Part I, Item 1A: “Risk Factors” of this Annual Report on Form 10-K and other risks and uncertainties detailed in this and our other reports and filings with the Securities and Exchange Commission, or SEC. The forward-looking statements in this Annual Report on Form 10-K represent our views as of the date of this Annual Report on Form 10-K. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

PART I

ITEM 1. BUSINESS

Company Overview

Soleno Therapeutics is focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. Our lead candidate, referred to as DCCR, a once-daily oral tablet for the treatment of Prader-Willi Syndrome, or PWS, a complex metabolic/neurobehavioral disorder, is currently being evaluated in a Phase III clinical development program.

On March 7, 2017, we completed our merger, or the Merger, with Essentialis, Inc., a Delaware corporation, or Essentialis, in accordance with the Merger Agreement by and between Soleno Therapeutics and Essentialis dated December 22, 2016, or the Merger Agreement. After the Merger, our primary focus has been the development and commercialization of novel therapeutics for the treatment of rare diseases. Essentialis was a privately-held, clinical-stage biotechnology company focused on the development of breakthrough medicines for the treatment of rare diseases where there is increased mortality and risk of cardiovascular and endocrine complications. Prior to the Merger, Essentialis's efforts were focused primarily on developing and testing product candidates that target the ATP-sensitive potassium channel, a metabolically-regulated membrane protein whose modulation has the potential to impact a wide range of rare metabolic, cardiovascular, and CNS diseases. Essentialis had tested Diazoxide Choline Controlled Release tablets, or DCCR, as a treatment for PWS. DCCR has orphan designation for the treatment of PWS in the United States, or U.S., as well as in the European Union, or E.U.

We initially established our operations as a diversified healthcare company that developed and commercialized innovative diagnostics, devices and therapeutics addressing unmet medical needs, which consisted of: precision metering of gas flow technology marketed as Serenz® Allergy Relief, or Serenz; the CoSense® End-Tidal Carbon Monoxide (ETCO) Monitor, or CoSense, which measures ETCO and aids in the detection of excessive hemolysis, a condition in which red blood cells degrade rapidly and which can lead to adverse neurological outcomes; and, products that included temperature probes, scales, surgical tables, and patient surfaces.

Subsequent to the Merger with Essentialis described above, we determined to divest, sell or dispose of our business efforts focused on the development and commercialization of our Serenz and CoSense technologies. Our current research and development efforts are primarily focused on advancing our lead candidate, DCCR tablets for the treatment of PWS, through late-stage clinical development.

Diazoxide Choline Controlled-Release Tablets

DCCR tablets consist of the active ingredient diazoxide choline, a choline salt of diazoxide, which is a benzothiadiazine. Once solubilized from the formulation, diazoxide choline is rapidly converted to diazoxide prior to absorption. Diazoxide acts by stimulating ion flux through ATP-sensitive K^+ channels (K_{ATP}). Diazoxide appears to act on signs and symptoms of PWS in a variety of ways. Agonizing the KATP channel in the hypothalamus has the potential to address the hallmark symptom of PWS – hyperphagia – a chronic feeling of insatiable hunger; and may also reduce aggressive behaviors in patients with PWS.

In the U.S., diazoxide was first approved in 1973 as an intravenous formulation, for the emergency treatment of malignant hypertension. In 1976, immediate-release oral formulations including Proglycem® Oral Suspension and Capsules, or Proglycem, were approved and there has been nearly 40 years of use of the 2-3 times a day, orally-administered, drug product in the approved indications. In addition, there are also extensive data on short term and chronic use of Proglycem in children with congenital hyperinsulinism, or CHI, and in adults with insulinoma. Insulinoma patients tend to be older, with 50% of them over 70 years old. Published data have reported that the average duration of use of Proglycem in certain CHI and insulinoma patients is 5 years and 7 years, respectively.

DCCR tablets were formulated with the goals of improving the safety and bioavailability of orally-administered diazoxide and reducing the frequency of daily dosing required by current diazoxide formulations. Diazoxide choline is formulated into an extended-release tablet (DCCR) that lowers peak plasma concentration compared to diazoxide oral suspension and allows for the gradual release of diazoxide choline from DCCR, making it suitable for once-a-day dosing. The gradual release and absorption of diazoxide achieved using DCCR results in consistent intraday circulating drug levels. Once it enters circulation, diazoxide becomes extensively protein bound, however only the unbound drug is active and readily enters tissues. Thus, the continuous absorption of diazoxide from DCCR may result in higher levels of unbound diazoxide for a given administered dose. The extended release and absorption from the formulation, reduced intraday variability in circulating drug levels, and the potentially higher levels of unbound diazoxide makes DCCR tablets suitable for once daily dosing. Avoiding significant swings in circulating drug levels also has the potential to reduce adverse events which are often associated with transiently high circulating drug levels that often follow rapid absorption from immediate release product formulations.

Prader-Willi Syndrome

PWS is a rare, complex neurobehavioral/metabolic disorder which is due to the absence of normally active paternally expressed genes from the chromosome 15q11-q13 region. PWS is an imprinted condition with 70-75% of the cases due to a de novo deletion in the paternally inherited chromosome 15 11-q13 region, 20-30% from maternal uniparental disomy 15, or UPD, where the affected individual inherited 2 copies of chromosome from their mother and no copy from their father, and the remaining 2-5% from either microdeletions or epimutations of the imprinting center (i.e., imprinting defects; IDs). The Committee on Genetics of the American Academy of Pediatrics states PWS affects both genders equally and occurs in people from all geographic regions; its estimated incidence is 1 in 15,000 live births. The mortality rate among PWS patients is 3% a year across all ages and 7% in those over 30 years of age. The mean age of death reported from a 40-year mortality study in the U.S. was 29.5 ± 15 years (range: 2 months—67 years).

In addition to hyperphagia, typical behavioral disturbances associated with PWS include skin picking, difficulty with change in routine, obsessive and compulsive behaviors and mood fluctuations. The majority of older adolescent and adult PWS patients display some degree of aggressive or threatening behaviors including being verbally aggressive, seeking to intimidate others, being physically aggressive including attacking others, destroying property, throwing temper tantrums and directing rage or anger at others.

PWS is typically thought of as a genetic obesity. However, many PWS patients today may not be obese because of increasing awareness among families and caregivers leading to significant control of food and its intake. However, patients remain hyperphagic and will typically have a higher body fat and lower lean body mass content. They are prone to cardiometabolic issues such as abnormal lipid profiles, diabetes and hypertension. Other complications in PWS patients include greater risk for autistic symptomatology, psychosis, sleep disorders, distress, food stealing, withdrawal, sulking, nail-biting, hoarding and overeating, and more pronounced attention-deficit hyperactivity disorder symptoms, insistence on sameness, and their association with maladaptive conduct problems. Individuals with PWS show age-related increases in internalizing problems such as anxiety, sadness and a feeling of low self-esteem. Males are at greater risk for aggressive behavior, depression and dependent personality disorder and overall severity of psychopathology than females. Cognitively, most individuals with PWS function in the mild intellectually disability range with a mean IQ in the 60s to low 70s. The combination of food-related preoccupations and numerous maladaptive behaviors make it difficult for individuals with PWS to perform to their IQ potential.

Unmet Medical Needs in PWS

The target indication for DCCR is the treatment of PWS. Currently, the only approved treatment related to PWS is growth hormone which addresses the short stature associated with PWS, but has no effect on hyperphagia. A global patient survey conducted by the Foundation for Prader-Willi Research (n=779), found that 96.5% of respondents rated reducing hunger and 91.2% rated improving behavior around food as very important or most important symptom to be relieved by a new treatment - https://www.fpwr.org/pws-patient-voices. Physical function and body composition symptoms for which a high percentage of respondents indicated were very important or most important included: 92.9% indicated improving metabolic health (reduces fat / increases muscle) and 81.3% indicated the related symptom of improving activity and stamina. The behavioral and cognitive symptoms rated by respondents as very or most important were: 85.2% indicated reduction of obsessive/compulsive behavior, 84.6% indicated improvements to intellect/development, and 83.2% indicated reduction of temper outburst severity and frequency.

Therefore, there is a clear unmet need in the treatment of PWS to reduce hyperphagia and improve behaviors around food, and to reduce other behavioral and cognitive impacts of this complex disease. In addition, improving metabolic health is also an important unmet need.

Clinical Trials of DCCR for PWS

A Phase II clinical trial has been conducted to evaluate the safety and preliminary efficacy of DCCR in the treatment of PWS subjects. This study, PC025, was a single-center, randomized withdrawal study and enrolled 13 overweight and obese subjects with genetically-confirmed PWS who were between the ages of 11 and 21. The first phase of the study was open-label during which subjects were initiated on a DCCR dose that was escalated every 14 days at the discretion of the investigator. Any subject who showed any increase in resting energy expenditure and/or a reduction in hyperphagia from baseline at certain study visits would be designated a responder, whereas all others would be designated non-responders. This 10-week open-label treatment phase was followed by randomized double-blind, placebo-controlled, withdrawal phase.

Responders were randomized in a 1:1 ratio either to continue on active treatment at the dose they were treated with, or to the placebo equivalent of that dose for an additional 4 weeks. Of the 13 subjects who enrolled, 11 completed the open-label phase and all were designated as responders; the remaining two subjects had discontinued prematurely.

Key efficacy results included a statistically significant reduction in hyperphagia from baseline to the end of the open-label treatment phase. In addition, greater improvement in hyperphagia from baseline was observed in those subjects with moderate to severe hyperphagia who received higher DCCR doses. There was a significant improvement in the number of subjects reporting one or more aggressive and destructive behaviors. During the open-label treatment phase, a mean decrease in body fat mass and increases in lean body mass and lean body mass / fat mass ratio were seen. These changes were associated with a statistically significant reduction in waist circumference, consistent with the loss of visceral fat. Statistically significant reductions from baseline in LDL cholesterol and non-HDL cholesterol were observed. The change in triglycerides, while marked, did not reach statistical significance.

A Phase III clinical trial is currently being conducted to evaluate the efficacy and safety of DCCR in patients with genetically-confirmed PWS. This study, DESTINY PWS, is a multi-center, randomized, double-blind, placebo-controlled study with enrollment of approximately 105 children and adults with PWS. Subjects who complete the 15-week DESTINY PWS study may enroll in a long-term, safety extension study (C602). On each of March 14, 2019, and October 1, 2019 the Data Safety Monitoring Board (DSMB) recommended the continuation of our Phase III DESTINY PWS trial without any changes. The DSMB is a group of independent experts monitoring the safety of the DESTINY PWS study. The DSMB reviews safety information and can make recommendations to either continue the study without modification, modify the study or terminate the study due to safety concerns. In July 2018, the U.S. Food and Drug Administration designated the development program for investigation of DCCR for the treatment of PWS to be a Fast Track development program. Prior to this, diazoxide choline received orphan designation for the treatment of PWS in the U.S. and in the E.U.

On January 6, 2020, we announced that we had completed our target enrollment for DESTINY PWS and expect to report top-line data in the first half of 2020. Additionally, based on the interest of the clinical investigators and families, we continue to make DCCR available to patients enrolled in the current program. The Company has, therefore, extended the C602 open-label extension study, allowing interested patients and families to continue in the study for up to two additional years.

Safety of DCCR in the Treatment of PWS

Many of the adverse events in the Phase II study were common medical complications of PWS including ear and respiratory infections, hypersomnia, peripheral edema, skin picking and constipation. The most common adverse events that occurred during the PC025 study, regardless of the relationship to DCCR, included peripheral edema, hyperglycemia, impaired glucose tolerance, upper respiratory tract infections, ear infection, headache, somnolence, constipation, and bruises.

Regulatory Status of DCCR for the Treatment of PWS

Diazoxide choline is being developed in the U.S. under a current IND and is designated as an Orphan Drug for the treatment of PWS. We announced successful completion of a scientific advice meeting with the FDA on July 5, 2017. On September 25, 2017, we announced receipt of advice from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) regarding DCCR for the treatment of PWS. On October 12, 2017, we announced the receipt of a positive opinion from the Committee for Orphan Medicinal Products (COMP) of the EMA recommending Orphan Designation for diazoxide choline for the treatment of PWS. This designation was granted by the European Commission as EU/3/17/1941. We announced successful completion and receipt of minutes from an End-of-Phase II meeting with the FDA and confirmed alignment on key aspects of the Phase III study design, including the primary endpoint and duration of the trial on February 20, 2018. On July 30, 2018, we announced that DCCR was granted "Fast Track" designation for the treatment of PWS. Fast Track designation is intended to provide patients with serious conditions and unmet medical needs access to new drugs earlier by assisting their development and accelerating their review by the FDA. Fast Track designation allows additional meetings with the FDA to discuss our development plan to ensure the appropriate data are collected and encourages frequent written communication with the FDA regarding design of clinical trials and use of biomarkers. If certain criteria are met, DCCR may be eligible for "Accelerated Approval" and "Priority Review" and also "Rolling Review", which would allow us to submit to the FDA sections of our New Drug Application (NDA) as they are finished instead of waiting for all sections to be completed before submitting the marketing application.

Market opportunity

An estimated 300,000 to 400,000 individuals worldwide have PWS with a birth incidence ranging from 1:15,000 to 1:25,000. The numbers of identified PWS patients is growing at a rate that is higher than the rate of general population because of improved rates of diagnosis. DCCR may be the first effective treatment for hyperphagia in PWS patients to reach the market both in the U.S. and Europe and may therefore be likely to be used in a large proportion of patients.

Sales and Marketing

Newly diagnosed PWS patients tend to be treated by a multi-disciplinary team led by a pediatric endocrinologist. Many patients receive care at larger clinics devoted to PWS in university-associated hospitals or at children's hospitals. This concentration of care allows us to consider marketing DCCR without a partner by assembling a small, dedicated salesforce to target the limited number of major PWS treatment centers in the U.S. In contrast to the situation in the U.S., we are likely to need to identify a marketing partner for DCCR in Europe, Japan, and the rest of the world. The final decision on sales and marketing strategy will be made at a later date.

Pricing

We have not conducted a formal pricing analysis of DCCR in PWS. We anticipate that pricing at launch may be influenced by the product label negotiated with the FDA, pharmacoeconomic data developed to support pricing and the potential for greater sales under negotiated government contracts.

Competition

Currently, the only approved products for PWS are Genotropin® (somatropin), and Omnitrope® (somatropin) which are approved only for growth failure due to PWS. There are no approved products to address PWS-associated hyperphagia and behaviors, or for any other abnormalities associated with the disease. However, to our knowledge, there are a number of therapeutic products at various stages of clinical development for the treatment of PWS, including for hyperphagia, by Levo Therapeutics, Inc., Millendo Therapeutics, Inc., Rhythm Pharmaceuticals, Inc., Saniona AB, Insys Therapeutics, Inc., Inversago, Consynance, and GLWL Research, Inc.

Manufacturing

Pharmaceuticals

Our manufacturing strategy is to contract with third parties to manufacture our clinical and commercial API and drug product supplies.

The formulation and processes used to manufacture our products are proprietary, being covered by multiple issued U.S. patents and counterparts in other regions of the world, and we have agreements with various third-party manufacturers that are intended to restrict these manufacturers from using or revealing any unpublished proprietary information.

Our third-party manufacturers and corporate partners are independent entities who are subject to their own operational and financial risks over which we have no control. If we or any of these third-party manufacturers fail to perform as required, this could cause delays in our clinical trials and regulatory applications and submission.

Regulation of Pharmaceutical Manufacturing Processes

The manufacturing process for pharmaceutical products is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. We and our third-party manufacturers are subject to current Good Manufacturing Practices, which are extensive regulations governing manufacturing processes, stability testing, record keeping and quality standards as defined by the FDA and the EMA. Similar regulations and requirements are in effect in other countries.

Intellectual Property

DCCR Patent Portfolio

Our patent portfolio surrounding DCCR consists of five issued U.S. patents, one allowed U.S. patent and 10 pending U.S. applications. Our issued U.S. patents (no.'s 7,572,789, 7,799,777, 9,381,202, 9,757,384, 9,782,416, 10,058,557, 10,085,998, and 10,456,408) expire in 2026 to 2035. We also have one or more issued patents covering the product in the E.U., Canada, Japan, China, India, Hong Kong and Australia, and numerous patent applications being prosecuted at the national level in all major pharma markets around the world. The issued patents and pending patent applications include protection of:

- A large family of salts including diazoxide choline, the active ingredient in DCCR and all pharmaceutical formulations of those salts;
- Specific polymorphs (specific crystalline forms) of salts of diazoxide and all pharmaceutical formulations of those polymorphs;
- Methods of manufacture of diazoxide choline and specific crystalline forms;
- Methods to treat various diseases including PWS and other rare diseases with DCCR;
- Methods to treat obese, overweight and obesity-prone individuals with DCCR;
- Pharmaceutical formulations of diazoxide;
- Methods to treat various diseases including a number of aspects of PWS and other rare diseases with diazoxide; and
- Methods to treat various rare diseases, including PWS, with KATP channel agonists.

Government Regulation - Pharmaceuticals

Our operations and activities are subject to extensive regulation by government authorities in the United States and in other countries in which we elect to develop and/or commercialize our products. Our developmental drug products are subject to rigorous regulation. Federal and state statutes and regulations govern the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of our products. As a result of these regulations, product development and product approval processes are very expensive and time consuming.

A country’s regulatory agency, such as the FDA in the United States, or a region’s agency, such as the EMA for the European Union, must approve a drug before it can be sold in the respective country or countries. The general process for drug approval in the United States is summarized below. Many other countries, including countries in the European Union and Japan, have very similar regulatory approval processes.

Nonclinical Testing

Before a drug candidate in can be tested in humans, it must be studied in laboratory experiments and in animals to generate data to support the drug candidate’s potential benefits and/or safety. Additional nonclinical testing may be required during the clinical development process such as reproductive toxicology and juvenile toxicology studies. Carcinogenicity studies in two species are generally required for products intended for long-term use.

Investigational New Drug Exemption Application (IND)

The results of initial nonclinical tests, together with manufacturing information, analytical data and a proposed clinical trial protocol and other information, are submitted as part of an IND to the FDA. If the FDA does not identify significant issues during the initial 30-day IND review, the drug candidate can then be studied in human clinical trials to determine if the drug candidate is safe and effective. Each clinical trial protocol and/or amendment, new nonclinical data, and/or new or revised manufacturing information must be submitted to the IND, and the FDA has 30 days to complete its review of each submission.

Clinical Trials

These clinical trials involve three separate phases that often overlap, can take many years and are very expensive. These three phases, which are subject to considerable regulation, are as follows:

Phase I Studies. During Phase I studies, researchers test a new drug in normal volunteers who are healthy. In most cases, 20 to 80 healthy volunteers or people with the disease/condition participate in Phase 1. Phase I studies are closely monitored and gather information about how a drug interacts with the human body. Researchers adjust dosing schemes based on animal data to find out how much of a drug the body can tolerate and what its acute side effects are. As a Phase I trial continues, researchers answer research questions related to how it works in the body, the side effects associated with increased dosage, and early information about how effective it is to determine how best to administer the drug to limit risks and maximize possible benefits. This is important to the design of Phase II studies.

Phase II Studies. In Phase II studies, researchers administer the drug to a group of patients with the disease or condition for which the drug is being developed. Typically involving up to a few hundred patients, these studies are not large enough to show whether the drug will be beneficial. Instead, Phase II studies provide researchers with additional safety data. Researchers use these data to refine research questions, develop research methods, and design new Phase III research protocols.

Phase III Studies. Researchers design Phase III studies to demonstrate whether or not a product offers a treatment benefit to a specific population. Sometimes known as pivotal studies, these studies generally involve a larger number of participants than do Phase II studies. Phase III studies provide most of the safety data. In Phase II studies, it is possible that less common side effects might have gone undetected. Because these studies are larger and longer in duration, the results are more likely to show long-term or rare side effects.

For each clinical trial, an independent IRB or independent ethics committee (IEC), covering each site proposing to conduct a clinical trial must review and approve the plan for any clinical trial and informed consent information for subjects before the trial commences at that site and it must monitor the study until completed. The FDA, other heath authority, the IRB/IEC, or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk or for failure to comply with the IRB/IEC's requirements, or may impose other conditions.

Clinical trials involve the administration of an investigational drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Sponsors of clinical trials generally must register and report, at the NIH-maintained website ClinicalTrials.gov, key parameters of certain clinical trials.

At any point in this process, the development of a drug candidate can be stopped for a number of reasons including safety concerns and lack of treatment benefit. We cannot be certain that any clinical trials that we are currently conducting or any that we conduct in the future will be completed successfully or within any specified time period. We may choose, or FDA may require us, to delay or suspend our clinical trials at any time if it appears that the patients are being exposed to an unacceptable health risk or if the drug candidate does not appear to have sufficient treatment benefit.

FDA Approval Process

When we believe that the data from our clinical trials show an adequate level of safety and efficacy, we would intend to submit an application to market the drug for a particular use, an NDA or BLA with the FDA. The FDA may hold a public hearing where an independent advisory committee of expert advisors asks additional questions and makes recommendations regarding the drug candidate. This committee makes recommendations to the FDA that are not binding but are generally followed by the FDA. If the FDA agrees that the compound has met the required level of safety and efficacy for a particular use, it will allow the drug product to be marketed in the United States and sold for that use. It is not unusual, however, for the FDA to reject an application because it believes that the risks of the drug candidate outweigh the purported benefit or because it does not believe that the data submitted are reliable or conclusive. The FDA may also issue a Complete Response Letter, or CRL, to indicate that the review cycle for an application is complete and that the application is not ready for approval. CRLs generally outline the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when the deficiencies have been addressed to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

The FDA may also require Phase IV non-registrational studies to explore scientific questions to further characterize safety and efficacy during commercial use of our drug. The FDA may also require us to provide additional data or information, improve our manufacturing processes, procedures or facilities or may require extensive surveillance to monitor the safety or benefits of our product candidates if it determines that our filing does not contain adequate evidence of the safety and benefits of the drug. In addition, even if the FDA approves a drug, it could limit the uses of the drug. The FDA can withdraw approvals if it does not believe that we are complying with regulatory standards or if problems are uncovered or occur after approval.

In addition to obtaining FDA approval for our drug, the manufacturing facilities of the companies who manufacture our drugs for us must also be approved. These facilities are subject to periodic inspections by the FDA. The FDA must also approve foreign establishments that manufacture products to be sold in the United States and these facilities are subject to periodic regulatory inspection.

Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems are identified after the product reaches the market. In addition, the FDA may require post-approval testing, including Phase IV studies, and surveillance programs to monitor the effect of approved products which have been commercialized, and the FDA has the authority to prevent or limit further marketing of a product based on the results of these post-marketing programs. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label, and, even if the FDA approves a product, it may limit the approved indications for use for the product or impose other conditions, including labeling or distribution restrictions or other risk-management mechanisms. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, the sponsor may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require the development of additional data or conduct of additional pre-clinical studies and clinical trials.

Drugs that treat serious or life-threatening diseases and conditions that are not adequately addressed by existing drugs, and for which the development program is designed to address the unmet medical need, may be designated as fast track and/or breakthrough candidates by the FDA and may be eligible for accelerated and priority review.

Drugs that are developed for rare diseases (i.e., in the U.S., the disease or condition has an prevalence of less than 200,000 persons; in the E.U., the prevalence of the condition must be not more than 5 in 10,000) can be designated as “Orphan Drugs”. In the U.S., orphan-designated drugs are granted up to 7-year market exclusivity. In the E.U., products granted orphan designation are subject to reduced fees for protocol assistance, marketing authorization applications, inspections before authorization, applications for changes to marketing authorizations, and annual fees, access to the centralized authorization procedure, and 10 years of market exclusivity.

Ongoing Regulation

Once a pharmaceutical product is approved, a product will be subject to pervasive and continuing regulation by the FDA, EMA, and other health authorities, including, among other things, recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are subject to periodic unannounced inspections by the FDA and state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and generally require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP or QSR 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 cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market, though the FDA must provide an application holder with notice and an opportunity for a hearing in order to withdraw its approval of an application. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates the marketing, labeling, advertising and promotion of drug and device products that are placed on the market. The Federal Trade Commission, or the FTC, also regulates the promotion and advertising of consumer products. While physicians may prescribe drugs and devices for off label uses, manufacturers may only promote for the approved indications and in accordance with the provisions of the approved label. Manufacturers may not promote a drug that is still under development and has not been approved by the FDA. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses, and a company that is found to have improperly promoted off label uses may be subject to significant liability.

Drugs are also subject to extensive regulation outside of the United States. In the European Union, there is a centralized approval procedure that authorizes marketing of a product in all countries of the European Union through a single application and review process. If this centralized approval procedure is not used, approval in one country of the European Union can be used to obtain approval in another country of the European Union under one of two simplified application processes: the mutual recognition procedure or the decentralized procedure, both of which rely on the principle of mutual recognition. After receiving regulatory approval through any of the European registration procedures, separate pricing and reimbursement approvals are also required in most countries. The European Union also has requirements for approval of manufacturing facilities for all products that are approved for sale by the European regulatory authorities.

Additional Government Regulations

HIPAA and Other Privacy Laws

HIPAA, established for the first-time comprehensive protection for the privacy and security of health information. The HIPAA standards apply to three types of organizations, or "Covered Entities": health plans, healthcare clearing houses, and healthcare providers which conduct certain healthcare transactions electronically. Covered Entities and their Business Associates must have in place administrative, physical, and technical standards to guard against the misuse of individually identifiable health information. Because we are a healthcare provider and we conduct certain healthcare transactions electronically, we are presently a Covered Entity, and we must have in place the administrative, physical, and technical safeguards required by HIPAA, HITECH and their implementing regulations. Additionally, some state laws impose privacy protections more stringent than HIPAA. Most of the institutions and physicians from which we obtain biological specimens that we use in our research and validation work are Covered Entities and must obtain proper authorization from their patients for the subsequent use of those samples and associated clinical information. We may perform future activities that may implicate HIPAA, such as providing clinical laboratory testing services or entering into specific kinds of relationships with a Covered Entity or a Business Associate of a Covered Entity.

If we or our operations are found to be in violation of HIPAA, HITECH or their implementing regulations, we may be subject to penalties, including civil and criminal penalties, fines, and exclusion from participation in U.S. federal or state health care programs, and the curtailment or restructuring of our operations. HITECH increased the civil and criminal penalties that may be imposed against Covered Entities, their 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.

Our activities must also comply with other applicable privacy laws. For example, there are also international privacy laws that impose restrictions on the access, use, and disclosure of health information. All of these laws may impact our business. Our failure to comply with these privacy laws or significant changes in the laws restricting our ability to obtain tissue samples and associated patient information could significantly impact our business and our future business plans.

Federal and State Billing and Fraud and Abuse Laws

Antifraud Laws/Overpayments. As participants in federal and state healthcare programs, we are subject to numerous federal and state antifraud and abuse laws. Many of these antifraud laws are broad in scope, and neither the courts nor government agencies have extensively interpreted these laws. Prohibitions under some of these laws include:

- the submission, or causing the submission of, false claims or false information to government programs;
- deceptive or fraudulent conduct;
- performing medically unnecessary procedures; and
- prohibitions in defrauding private sector health insurers.

We could be subject to substantial penalties for violations of these laws, including denial of payment and refunds, suspension of payments from Medicare, Medicaid or other federal healthcare programs and exclusion from participation in the federal healthcare programs, as well as civil monetary and criminal penalties and imprisonment. One of these statutes, the False Claims Act, is a key enforcement tool used by the government to combat healthcare fraud. The False Claims Act imposes liability on any person who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. In addition, violations of the federal physician self-referral laws, such as the Stark laws discussed below, may also violate false claims laws.

Liability under the False Claims Act can result in treble damages and imposition of penalties. For example, we could be subject to penalties of $11,181 to $22,363 per false claim, and each use of our product could potentially be part of a different claim submitted to the government. Separately, the HHS office of the Office of Inspector General, or OIG, can exclude providers found liable under the False Claims Act from participating in federally funded healthcare programs, including Medicare and Medicaid. The steep penalties that may be imposed on laboratories and other providers under this statute may be disproportionate to the relatively small dollar amounts of the claims made by these providers for reimbursement. In addition, even the threat of being excluded from participation in federal healthcare programs can have significant financial consequences on a provider.

Numerous federal and state agencies enforce the antifraud and abuse laws. In addition, private insurers may also bring private actions. In some circumstances, private whistleblowers are authorized to bring fraud suits on behalf of the government against providers and are entitled to receive a portion of any final recovery.

Federal and State "Self-Referral" and "Anti-Kickback" Restrictions

Self-Referral law. We are subject to a federal "self-referral" law, commonly referred to as the "Stark" law, which provides that physicians who, personally or through a family member, have ownership interests in or compensation arrangements with a laboratory are prohibited from making a referral to that laboratory for laboratory tests reimbursable by Medicare, and also prohibits laboratories from submitting a claim for Medicare payments for laboratory tests referred by physicians who, personally or through a family member, have ownership interests in or compensation arrangements with the testing laboratory. The Stark law contains a number of specific exceptions which, if met, permit physicians who have ownership or compensation arrangements with a testing laboratory to make referrals to that laboratory and permit the laboratory to submit claims for Medicare payments for laboratory tests performed pursuant to such referrals.

We are subject to comparable state laws, some of which apply to all payors regardless of source of payment, and do not contain identical exceptions to the Stark law. For example, we are subject to a North Carolina self-referral law that prohibits a physician investor from referring to us any patients covered by private, employer-funded or state and federal employee health plans. The North Carolina self-referral law contains few exceptions for physician investors in securities that have not been acquired through public trading but will generally permit us to accept referrals from physician investors who buy their shares in the public market.

We have several stockholders who are physicians in a position to make referrals to us. We have included within our compliance plan procedures to identify requests for testing services from physician investors and we do not bill Medicare, or any other federal program, or seek reimbursement from other third-party payors, for these tests.

Providers are subject to sanctions for claims submitted for each service that is furnished based on a referral prohibited under the federal self-referral laws. These sanctions include denial of payment and refunds, civil monetary payments and exclusion from participation in federal healthcare programs and civil monetary penalties, and they may also include penalties for applicable violations of the False Claims Act, which may require payment of up to three times the actual damages sustained by the government, plus civil penalties of $11,181 to $22,363 for each separate false claim. Similarly, sanctions for violations under the North Carolina self-referral laws include refunds and monetary penalties.

Anti-Kickback Statute. The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payment, ownership interests and providing anything at less than its fair market value. The reach of the Anti-Kickback Statute was also broadened by the PPACA, which, among other things, amends the intent requirement of the federal Anti-Kickback Statute and certain criminal healthcare fraud statutes, effective March 23, 2010. Pursuant to the statutory amendment, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, PPACA provides 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 False Claims Act or the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Sanctions for violations of the federal Anti-Kickback Statute may include imprisonment and other criminal penalties, civil monetary penalties and exclusion from participation in federal healthcare programs.

The OIG has criticized a number of the business practices in the clinical laboratory industry as potentially implicating the Anti-Kickback Statute, including compensation arrangements intended to induce referrals between laboratories and entities from which they receive, or to which they make, referrals. In addition, the OIG has indicated that “dual charge” billing practices that are intended to induce the referral of patients reimbursed by federal healthcare programs may violate the Anti-Kickback Statute.

Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs, and do not contain identical safe harbors. For example, North Carolina has an anti-kickback statute that prohibits healthcare providers from paying any financial compensation for recommending or securing patient referrals. Penalties for violations of this statute include license suspension or revocation or other disciplinary action. Other states have similar anti-kickback prohibitions.

Both the federal Anti-Kickback Statute and the North Carolina anti-kickback law are broad in scope. The anti-kickback laws clearly prohibit payments for patient referrals. Under a broad interpretation, these laws could also prohibit a broad array of practices involving remuneration where one party is a potential source of referrals for the other.

If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in U.S. federal or state health care programs, and the curtailment or restructuring of our operations. To the extent that any product we make is sold in a foreign country in the future, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals. To reduce the risks associated with these various laws and governmental regulations, we have implemented a compliance plan. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

U.S. Healthcare Reform

In March 2010, the PPACA was enacted, which includes measures that have or will significantly change the way healthcare is financed by both governmental and private insurers. Beginning in August 2013, the PPACA and its implementing regulations requires drug and medical device manufacturers to track certain financial arrangements with physicians and teaching hospitals, including any “transfer of value” made or distributed to such entities, as well as any investment interests held by physicians and their immediate family members. Manufacturers are required to report this information to Centers for Medicare & Medicaid Services on an annual basis. Failure to make timely reports to CMS can subject us to significant civil penalties. Various states have also implemented regulations prohibiting certain financial interactions with healthcare professionals or mandating public disclosure of such financial interactions. We may incur significant costs to comply with such laws and regulations now or in the future.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the

U.S. to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Other Corporate Transactions

Joint Venture Agreement and Issuance of Shares by Capnia, Inc.

In December 2017, we entered into a joint venture agreement, or the Joint Venture Agreement, with OptAsia Healthcare Limited, a Hong Kong company, or OAHL, with respect to CoSense with the intent to sell shares of Capnia, Inc., our previously wholly-owned subsidiary into which our CoSense business had been transferred, to OAHL. Under the terms of the Joint Venture Agreement, OAHL agreed to invest up to $2.2 million to purchase shares of our Capnia subsidiary on an incremental quarterly basis commencing in December 2017. OAHL was also responsible for funding a portion of the Capnia operations. For financial reporting purposes, Capnia’s assets, liabities and results of operations had historically been consolidated with ours.

In October 2018, we determined and agreed that the cumulative investment made by OAHL exceeded $1.2 million as dictated by the Joint Venture Agreement between us and OAHL. Accordingly, on October 16, 2018, Capnia issued 1,690,322 shares of its common stock to OAHL, representing 53% of its outstanding shares. After the issuance by Capnia, we no longer held a controlling interest in Capnia. The transfer of the 53% ownership stake resulted in the deconsolidation of Capnia from our financial statements and a $1.9 million gain recognized in the fourth quarter of 2018. Our remaining 47% investment in Capnia was then classified as an equity method investment.

In September 2019, we sold our remaining 47% investment in Capnia to Sinon Investments LLC, or Sinon, for a total purchase price of $500,000. Following the transaction, we have no interest remaining in Capnia and the previous joint venture agreement with OAHL has been terminated.

2018 PIPE Offering

On December 19, 2018, we entered into a Securities Purchase Agreement with certain purchasers, pursuant to which we sold and issued 10,272,375 units at a price per unit of $1.61, for aggregate gross proceeds of $16.5 million. Each unit consisted of one share of our common stock and a warrant to purchase 0.05 shares of our common stock at an exercise price of $2.00 per share, for an aggregate of 10,272,375 shares of common stock and corresponding warrants to purchase an aggregate of 513,617 shares of common stock, together with the shares of common stock are referred to as the 2018 Resale Shares. We also granted certain registration rights to these stockholders, pursuant to which, among other things, the Company prepared and filed a registration statement with the SEC to register for resale the 2018 Resale Shares. The registration statement was declared effective in April 2019. This offering is referred to herein as the 2018 PIPE Offering and the warrants issued therein are referred to as the 2018 PIPE Warrants.

2019 Public Offering

On October 25, 2019, we sold 12,841,667 shares of common stock in an underwritten public offering at a price of $1.20 per share for net proceeds of $14.5 million.

Employees

As of December 31, 2019, we had twelve full-time employees and thirteen full-time or part-time consultants providing services to us. None of our employees is represented by a labor union or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Corporate and Available Information

Our principal corporate offices are located at 203 Redwood Shores Parkway, Suite 500, Redwood City, California 94065 and our telephone number is (650) 213-8444. We were incorporated in Delaware on August 25, 1999. Our internet address is www.soleno.life. We make available on our website, free of charge, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to those reports, as soon as reasonably practicable after we electronically file such materials with, or furnish it to, the Securities Exchange and Commission. Our Securities Exchange and Commission reports can be accessed through the Investor Relations section of our internet website. The information found on our internet website is not part of this or any other report we file with or furnish to the Securities Exchange and Commission.

ITEM 1A. RISK FACTORS

An investment in our securities has a high degree of risk. Before you invest you should carefully consider the risks and uncertainties described below together with all of the other information in this Annual Report on Form 10-K, including our consolidated financial statements and related notes. If any of the following risks actually occur, our business, operating results and financial condition could be harmed, and the value of our stock could go down. This means you could lose all or a part of your investment.

Risks related to our financial condition and capital requirements

We are primarily a clinical-stage company with no approved products, which makes assessment of our future viability difficult.

We are primarily a clinical-stage company, with a relatively limited operating history and with no approved therapeutic products or revenues from the sale of therapeutic products. As a result, there is limited information for investors to use when assessing our future viability as a company focused primarily on therapeutic products and our potential to successfully develop product candidates, conduct clinical trials, manufacture our products on a commercial scale, obtain regulatory approval and profitably commercialize any approved products.

We are significantly dependent upon the success of DCCR, our sole therapeutic product candidate.

We invest a significant portion of our efforts and financial resources in the development of DCCR for the treatment of PWS, a rare complex genetic neurobehavioral/metabolic disease. Our ability to generate product revenues, which may not occur for the foreseeable future, if ever, will depend heavily on the successful development, regulatory approval, and commercialization of DCCR.

Any delay or impediment in our ability to obtain regulatory approval to commercialize in any region, or, if approved, obtain coverage and adequate reimbursement from third-parties, including government payors, for DCCR, may cause us to be unable to generate the revenues necessary to continue our research and development pipeline activities, thereby adversely affecting our business and our prospects for future growth. Further, the success of DCCR will depend on a number of factors, including the following:

- obtain a sufficiently broad label that would not unduly restrict patient access;
- receipt of marketing approvals for DCCR in the U. S. and E. U.;
- building an infrastructure capable of supporting product sales, marketing, and distribution of DCCR in territories where we pursue commercialization directly;
- establishing commercial manufacturing arrangements with third party manufacturers;
- establishing commercial distribution agreements with third party distributors;
- launching commercial sales of DCCR, if and when approved, whether alone or in collaboration with others;
- acceptance of DCCR, if and when approved, by patients, the medical community, and third-party payers;
- the regulatory approval pathway that we pursue for DCCR in the United States;
- effectively competing with other therapies;
- a continued acceptable safety profile of DCCR following approval;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity;
- protecting our rights in our intellectual property portfolio; and
- obtaining a commercially viable price for our products.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize DCCR, which would materially harm our business.

We may need additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all, which would force us to delay, reduce or suspend our research and development programs and other operations or commercialization efforts. Raising additional capital may subject us to unfavorable terms, cause dilution to our existing stockholders, restrict our operations, or require us to relinquish rights to our planned products and technologies.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As of December 31, 2019, we have incurred significant operating losses since inception and continue to generate losses from operations and have an accumulated deficit of $157.8 million. These matters raise substantial doubt about our ability to continue as a going concern. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should we be unable to continue as a going concern.

Commercial results have been limited and we have not generated significant revenues. We cannot assure our stockholders that our revenues will be sufficient to fund our operations, including expenses related to our current ongoing clinical trial of DCCR. If adequate funds are not available, we may be required to curtail our operations significantly or to obtain funds through dilutive financings or entering into arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies or products that we would not otherwise relinquish.

At December 31, 2019, our cash balance was $20.7 million. We intend to raise additional capital, either through debt or equity financings to achieve our business plan objectives, including increased expenses related to additional resources being deployed to manage enrollment of patients and other activities related to our current ongoing clinical trial of DCCR. We believe that we can be successful in obtaining additional capital; however, no assurance can be provided that we will be able to do so. There is no assurance that any funds raised will be sufficient to enable us to attain profitable operations or continue as a going concern. To the extent that we are unsuccessful, we may need to curtail or cease our operations and implement a plan to extend payables or reduce overhead until sufficient additional capital is raised to support further operations. There can be no assurance that such a plan will be successful.

We do not have any material committed external source of funds or other support for our commercialization and development efforts. Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never achieve, we expect to finance future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. Additional financing may not be available to us when we need it, or it may not be available on favorable terms. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our current and planned products, technologies, future revenue streams or research programs, or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of, or suspend one or more of our clinical studies or research and development programs or our commercialization efforts.

We have a limited commercialization history and have incurred significant losses since our inception, and we anticipate that we will continue to incur substantial losses for the foreseeable future. We transitioned to be primarily a research and development company, which, together with our limited operating history, makes it difficult to evaluate our business and assess our future viability.

We are a developer of therapeutics with a limited commercialization history. Evaluating our performance, viability or future success will be more difficult than if we had a longer operating history or approved products for sale on the market. We continue to incur significant research and development and general and administrative expenses related to our operations. Investment in product development is highly speculative, because it entails substantial upfront capital expenditures and significant risk that any planned product will fail to demonstrate adequate accuracy or clinical utility. We have incurred significant operating losses in each year since our inception and expect that we will not be profitable for an indefinite period of time. As of December 31, 2019, we had an accumulated deficit of $157.8 million.

We expect that our future financial results will depend primarily on our success in developing, launching, selling and supporting our products. This will require us to be successful in a range of activities, including clinical trials, manufacturing, marketing and selling our products. We are only in the preliminary stages of some of these activities. We may not succeed in these activities and may never generate revenue that is sufficient to be profitable in the future. Even if we are profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to achieve sustained profitability would depress the value of our company and could impair our ability to raise capital, expand our business, diversify our planned products, market our current and planned products, or continue our operations.

We currently have generated limited product revenue and may never become profitable.

To date, we have not generated significant revenues to achieve profitability. Our ability to generate significant revenue from product sales and achieve profitability will depend upon our ability, alone or with any future collaborators, to successfully commercialize products that we may develop, in-license or acquire in the future. Our ability to generate revenue from product sales from planned products also depends on a number of additional factors, including our ability to:

- develop a commercial organization capable of sales, marketing and distribution of any products for which we obtain marketing approval in markets where we intend to commercialize independently;
- achieve market acceptance of our current and future products, if any;
- set a commercially viable price for our current and future products, if any;
- establish and maintain supply and manufacturing relationships with reliable third parties, and ensure adequate and legally compliant manufacturing to maintain that supply;

- obtain coverage and adequate reimbursement from third-party payors, including government and private payors;
- find suitable global and U.S. distribution partners to help us market, sell and distribute our products in other markets;
- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities;
- complete development activities successfully and on a timely basis;
- establish, maintain and protect our intellectual property rights and avoid third-party patent interference or patent infringement claims; and
- attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with product development and commercialization, including that our planned products may not advance through development, achieve the endpoints of applicable clinical trials or obtain approval, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we decide, or are required by the FDA or foreign regulatory authorities, to perform studies or clinical trials in addition to those that we currently anticipate.

Even if we are able to generate significant revenue from the sale of any of our products that may be approved or commercialized, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or shut down our operations.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or below our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into collaboration agreements with other companies that include development funding and significant upfront and milestone payments or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under any potential future collaboration and license agreements and sales of our products, if approved. These upfront and milestone payments may vary significantly from period to period, and any such variance could cause a significant fluctuation in our operating results from one period to the next. In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our Board of Directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- our ability to enroll patients in clinical trials and the timing of enrollment;
- the cost and risk of initiating sales and marketing activities;
- the timing and cost of, and level of investment in, research and development activities relating to our planned products, which will change from time to time;
- the cost of manufacturing our products may vary depending on FDA and other regulatory requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional planned products and technologies;
- the design, timing and outcomes of clinical studies;

- changes in the competitive landscape of our industry, including consolidation among our competitors or potential partners;
- any delays in regulatory review or approval in the U.S. or globally, of any of our planned products;
- the level of demand for our products may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our future products, if approved, and existing and potential future drugs that compete with our planned products;
- competition from existing and potential future offerings that compete with our products;
- our ability to commercialize our products inside and outside of the U.S., either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

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, asset purchases and sales, 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, could not result in perceived benefits that were contemplated upon entering into the transaction, and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations, solvency and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown and contingent 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 acquisitions;
- higher than expected acquisition and integration costs;
- the timing and likelihood of payment of milestones or royalties;
- write-downs of assets or goodwill or impairment charges;
- increased operating expenditures, including additional research, development and sales and marketing expenses;
- increased amortization expenses;

- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel; and
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership.

Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above or that we will achieve an economic benefit that justifies such transactions, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

We may not be able to enter into strategic transactions on a timely basis or on acceptable terms, which may impact our development and commercialization plans.

We have relied, and expect to continue to rely, on strategic transactions, which include in-licensing, out-licensing, purchases and sales of assets, and other ventures. The terms of any additional strategic transaction that we may enter into may not be favorable to us, and the contracts governing such strategic transaction may be subject to differing interpretations exposing us to potential litigation. We may also be restricted under existing collaboration or licensing arrangements from entering into future agreements on certain terms with potential strategic partners. We may not be able to negotiate additional strategic transactions on a timely basis, on acceptable terms, or at all. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our products or bring them to market and generate product revenue. Furthermore, there is no assurance that any such transaction will be successful or that we will derive an economic benefit as a result.

Risks related to the development and commercialization of our products

We may not be successful in commercializing our approved products

Commercialization of products is subject to a variety of regulations regarding the manner in which potential customers may be engaged, the manner in which products may be lawfully advertised, and the claims that can be made for the benefits of the product, among other things. Our lack of experience with product launches may expose us to a higher than usual level of risk of non-compliance with these regulations, with consequences that may include fines or the removal of our approved products from the marketplace by regulatory authorities.

If we are unable to execute our sales and marketing strategy for our products, and are unable to gain acceptance in the market, we may be unable to generate sufficient revenue to sustain our business.

Although we believe that DCCR and our other planned products represent promising commercial opportunities, our products may never gain significant acceptance in the marketplace and therefore may never generate substantial revenue or profits for us. We will need to establish a market for DCCR globally and build these markets through physician education, awareness programs, and other marketing efforts. Gaining acceptance in medical communities depends on a variety of factors, including clinical data published or reported in reputable contexts and word-of-mouth between physicians. The process of publication in leading medical journals is subject to a peer review process and peer reviewers may not consider the results of our studies sufficiently novel or worthy of publication. Failure to have our studies published in peer-reviewed journals may limit the adoption of our products. Our ability to successfully market our products will depend on numerous factors, including:

- the outcomes of clinical utility studies of such products in collaboration with key thought leaders to demonstrate our products' value in informing important medical decisions such as treatment selection;
- the success of our distribution partners;
- whether healthcare providers believe such tests provide clinical utility;
- whether the medical community accepts that such tests are sufficiently sensitive and specific to be meaningful in-patient care and treatment decisions; and

- whether hospital administrators, health insurers, government health programs and other payers will cover and pay for such tests and, if so, whether they will adequately reimburse us.

We are relying, or will rely, on third parties with whom we are directly engaged with, but who we do not control, to distribute and sell our products. If these distributors are not committed to our products or otherwise run into their own financial or other difficulties, it may result in failure to achieve widespread market acceptance of our products, and would materially harm our business, financial condition and results of operations.

If we are unable to implement our sales, marketing, distribution, training and support strategies or enter into agreements with third parties to perform these functions in markets outside of the U.S. and E.U., we will not be able to effectively commercialize DCCR and may not reach profitability.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of therapeutic products. To achieve commercial success for DCCR, if and when we obtain marketing approval, we will need to establish a sales and marketing organization.

In the future, we expect to build a targeted sales, marketing, training and support infrastructure to market DCCR in the U.S. and E.U. and to opportunistically establish collaborations to market, distribute and support DCCR outside of the U.S. and E.U. There are risks involved with establishing our own sales, marketing, distribution, training and support capabilities. For example, recruiting and training sales and marketing personnel is expensive and time consuming and could delay any product launch. If the commercial launch of DCCR is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales, marketing, training and support personnel.

Factors that may inhibit our efforts to commercialize DCCR on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe DCCR or any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- efforts by our competitors to commercialize products at or about the time when our product candidates would be coming to market.

If we are unable to establish our own sales, marketing, distribution, training and support capabilities and instead enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, are likely to be lower than if we were to market, sell and distribute DCCR ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute DCCR or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to commercialize DCCR effectively. If we do not establish sales, marketing, distribution, training and support capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing DCCR and achieving profitability, and our business would be harmed.

If physicians decide not to order our products in significant numbers, we may be unable to generate sufficient revenue to sustain our business.

To generate demand for our current and planned products, we will need to educate physicians and other health care professionals on the clinical utility, benefits and value of the tests we provide through published papers, presentations at scientific conferences, educational programs and one-on-one education sessions by members of our sales force. In addition, we will need support of hospital administrators that the clinical and economic utility of our products justifies payment for the device and consumables at adequate pricing levels. We need to hire additional commercial, scientific, technical and other personnel to support this process.

If our products do not continue to perform as expected, our operating results, reputation and business will suffer.

Our success depends on the market's confidence that our products can provide reliable, high-quality results or treatments. We believe that our customers are likely to be particularly sensitive to any test defects and errors in our products, and prior products made by other companies for the same diagnostic purpose have failed in the marketplace, in part as a result of poor accuracy. As a result, the failure of our current and planned products to perform as expected would significantly impair our reputation and the clinical usefulness of such tests. Reduced sales might result, and we may also be subject to legal claims arising from any defects or errors.

If clinical studies of any of our planned products fail to demonstrate safety and effectiveness to the satisfaction of the FDA or similar regulatory authorities outside the U.S. or do not otherwise produce positive results, we may incur additional costs, experience delays in completing or ultimately fail in completing the development and commercialization of our planned products.

Before obtaining regulatory approval for the sale of any planned product we must conduct extensive clinical studies to demonstrate the safety and effectiveness of our planned products in humans. Clinical studies are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. A failure of one or more of our clinical studies could occur at any stage of testing.

Numerous unforeseen events during, or as a result of, clinical studies could occur, which would delay or prevent our ability to receive regulatory approval or commercialize any of our planned products, including the following:

- clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical studies or abandon product development programs;
- the number of patients required for clinical studies may be larger than we anticipate, enrollment in these clinical studies may be insufficient or slower than we anticipate, or patients may drop out of these clinical studies at a higher rate than we anticipate;
- the cost of clinical studies or the manufacturing of our planned products may be greater than we anticipate;
- third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical studies of our planned products for various reasons, including a finding that our planned products have unanticipated serious side effects or other unexpected characteristics or that the patients are being exposed to unacceptable health risks;
- regulators may not approve our proposed clinical development plans;
- regulators or independent institutional review boards, or IRBs, may not authorize us or our investigators to commence a clinical study or conduct a clinical study at a prospective study site;
- regulators or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; and
- the supply or quality of our planned products or other materials necessary to conduct clinical studies of our planned products may be insufficient or inadequate.

If we or any future collaboration partners are required to conduct additional clinical trials or other testing of any planned products beyond those that we contemplate, if those clinical studies or other testing cannot be successfully completed, if the results of these studies or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our planned products;

- not obtain marketing approval at all;
- obtain approval for indications that are not as broad as intended;
- have the product removed from the market after obtaining marketing approval;
- be subject to additional post-marketing testing requirements; or
- be subject to restrictions on how the product is distributed or used.

Our product development costs will also increase if we experience delays in testing or approvals. We do not know whether any clinical studies will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical study delays also could shorten any periods during which we may have the exclusive right to commercialize our planned products or allow our competitors to bring products to market before we do, which would impair our ability to commercialize our planned products and harm our business and results of operations.

If we fail to obtain regulatory approval for DCCR in the U.S. and E.U., our business would be harmed.

We are required to obtain regulatory approval for each indication we are seeking before we can market and sell DCCR in a particular jurisdiction, for such indication. Our ability to obtain regulatory approval of DCCR depends on, among other things, successful completion of clinical trials by demonstrating efficacy with statistical significance and clinical meaning, and safety in humans. The results of our current and future clinical trials may not meet the FDA, the European Medicines Agency, or EMA, or other regulatory agencies' requirements to approve DCCR for marketing under any specific indication, and these regulatory agencies may otherwise determine that our third parties' manufacturing processes, validation, and/ or facilities are insufficient to support approval. As such, we may need to conduct more clinical trials than we currently anticipate and upgrade the manufacturing processes and facilities, which may require significant additional time and expense, and may delay or prevent approval. If we fail to obtain regulatory approval in a timely manner, our commercialization of DCCR would be delayed and our business would be harmed.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, results of earlier studies and trials may not be predictive of future trial results, and our clinical trials may fail to adequately demonstrate the safety and efficacy of DCCR or other potential product candidates.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. A failure of one or more of our clinical trials can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later stage clinical trials. There is a high failure rate for drugs proceeding through clinical trials, and product candidates in later stages of clinical trials may fail to show the required safety and efficacy despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier clinical trials, and we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates.

We may experience delays in our clinical trials. We do not know whether future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of patients in a timely manner or be completed on schedule, if at all. Clinical trials can be delayed, suspended or terminated for a variety of reasons, including failure to:

- generate sufficient nonclinical, toxicology, or other in vivo or in vitro data, or clinical safety data to support the initiation or continuation of clinical trials;
- obtain regulatory approval, or feedback on trial design, to commence a trial;
- identify, recruit and train suitable clinical investigators;

- reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- obtain and maintain institutional review board, or IRB, approval at each clinical trial site;
- identify, recruit and enroll suitable patients to participate in a trial;
- have a sufficient number of patients complete a trial and/or return for post-treatment follow-up;
- ensure clinical investigators observe trial protocol or continue to participate in a trial;
- address any patient safety concerns that arise during the course of a trial;
- address any conflicts or compliance with new or existing laws, rule, regulations or guidelines;
- have a sufficient number of clinical trial sites to conduct the trials;
- timely manufacture sufficient quantities of product candidate suitable for use at the stage of clinical development; or
- raise sufficient capital to fund a trial.

Patient enrollment is a significant factor in the timing of clinical trials and 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' or caregivers' perceptions as to the potential advantages of the drug candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating or any investigational new drugs or treatment under development for the indications we are investigating.

There has recently been increased activity in the development of drugs to treat PWS. We are aware of eight other current or proposed clinical trials evaluating PWS therapies. If all of these clinical trials are ongoing concurrently, given the limited number of patients, it may hamper recruitment and enrollment of qualified patients for our current trial of DCCR in PWS.

We could also encounter delays if a clinical trial is suspended or terminated by us, by a data safety monitoring board for such trial or by the FDA or any other regulatory authority, or if the IRBs of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates for any reason, the commercial prospects of our product candidates may be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. 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.

We may be unable to obtain regulatory approval for DCCR or other potential product candidates. The denial or delay of any such approval would delay commercialization and have a material adverse effect on our potential to generate revenue, our business and our results of operations.

The research, development, testing, manufacturing, labeling, packaging, approval, promotion, advertising, storage, record keeping, marketing, distribution, post-approval monitoring and reporting, and export and import of drug products are subject to extensive regulation by the FDA, and by foreign regulatory authorities in other countries. The legislation and regulations differ from country to country. To gain approval to market our product candidates, we must provide development, manufacturing and clinical data that adequately demonstrates the safety and efficacy of the product for the intended indication. We have not yet obtained regulatory approval to market any of our product candidates in the U.S. or any other country. Our business depends upon obtaining these regulatory approvals. The FDA can delay, limit or deny approval of our product candidates for many reasons, including:

- our inability to satisfactorily demonstrate that the product candidates are safe and effective for the requested indication;
- the FDA's disagreement with our trial protocol or the interpretation of data from preclinical studies or clinical trials;
- the population studied in the clinical trial may not be sufficiently broad or representative to assess safety in the full population for which we seek approval;
- our inability to demonstrate that clinical or other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA's determination that additional preclinical or clinical trials are required;
- the FDA's non-approval of the formulation, labeling or the specifications of our product candidates;
- the FDA's failure to accept the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the potential for approval policies or regulations of the FDA to significantly change in a manner rendering our clinical data insufficient for approval.

Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA may grant approval contingent on the performance of costly additional post-approval clinical trials. The FDA may also approve our product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. To the extent we seek regulatory approval in foreign countries, we may face challenges similar to those described above with regulatory authorities in applicable jurisdictions. Any delay in obtaining, or inability to obtain, applicable regulatory approval for any of our product candidates would delay or prevent commercialization of our product candidates and would materially adversely impact our business, results of operations and prospects.

Even if any planned products receive regulatory approval, these products may fail to achieve the degree of market acceptance by physicians, patients, caregivers, healthcare payors and others in the medical community necessary for commercial success.

If any planned products receive regulatory approval from the FDA or other regulatory agencies in jurisdictions in which they are not currently approved, they may nonetheless fail to gain sufficient market acceptance by physicians, hospital administrators, patients, healthcare payors and others in the medical community. The degree of market acceptance of our planned products, if approved for commercial sale, will depend on a number of factors, including the following:

- the prevalence and severity of any side effects;
- their effectiveness and potential advantages compared to alternative treatments;
- the price we charge for our planned products;
- the willingness of physicians to change their current treatment practices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength or effectiveness of marketing and distribution support or partners; and
- the availability of third-party coverage or reimbursement.

If the market opportunity for DCCR is smaller than we believe it is, then our revenues may be adversely affected, and our business may suffer.

PWS is a rare disease, and as such, our projections of both the number of people who have this disease, as well as the subset of people with PWS who have the potential to benefit from treatment with our product candidate, are based on estimates.

Currently, most reported estimates of the prevalence of PWS are based on studies of small subsets of the population of specific geographic areas, which are then extrapolated to estimate the prevalence of the diseases in the broader world population. In addition, as new studies are performed the estimated prevalence of these diseases may change. There can be no assurance that the prevalence of PWS in the study populations, particularly in these newer studies, accurately reflects the prevalence of this disease in the broader world population. If our estimates of the prevalence of PWS, or of the number of patients who may benefit from treatment with our product candidates prove to be incorrect, the market opportunities for our product candidate may be smaller than we believe it is, our prospects for generating revenue may be adversely affected and our business may suffer.

DCCR is currently under development and we have no sales and distribution personnel, and limited marketing capabilities at the present time to commercialize DCCR, if we receive regulatory approval. If we are unable to develop a sales and marketing and distribution capability on our own or through collaborations or other marketing partners, we will not be successful in commercializing our products, or other planned products.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming, and could delay any product launch. If the commercial launch of a planned product for which we recruit a sales force and establish marketing capabilities is delayed, or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

To achieve commercial success for any approved product, we must either develop a sales and marketing infrastructure or outsource these functions to third parties. We also may not be successful entering into arrangements with third parties to sell and market our planned products or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively and could damage our reputation. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our planned products.

We may attempt to form partnerships with respect to our products, but we may not be able to do so, which may cause us to alter our development and commercialization plans and may cause us to terminate any such programs.

We may form strategic alliances, create joint ventures or collaborations, or enter into licensing agreements with third parties that we believe will more effectively provide resources to develop and commercialize our programs. For example, we currently intend to identify one or more new partners or distributors for the commercialization of our products.

We face significant competition in seeking appropriate strategic partners, and the negotiation process to secure favorable terms is time-consuming and complex. We may not be successful in our efforts to establish such a strategic partnership for any future products and programs on terms that are acceptable to us, or at all.

Any delays in identifying suitable collaborators and entering into agreements to develop or commercialize our future products could negatively impact the development or commercialization of our future products, particularly in geographic regions like the E.U., where we do not currently have development and commercialization infrastructure. Absent a partner or collaborator, we would need to undertake development or commercialization activities at our own expense. If we elect to fund and undertake development and commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we are unable to do so, we may not be able to develop our future products or bring them to market, and our business may be materially and adversely affected.

Our products may cause serious adverse side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial desirability of an approved label or result in significant negative consequences following any marketing approval.

The risk of failure of clinical development is high. It is impossible to predict when or if any planned products will prove safe enough to receive regulatory approval. Undesirable side effects caused by any of our products could cause us or regulatory authorities to interrupt, delay or halt clinical trials or could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. Additionally, if any of our planned products receives additional marketing approvals, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including:

- we may be forced to recall such product and suspend the marketing of such product;
- regulatory authorities may withdraw their approvals of such product;
- regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of such products;
- the FDA or other regulatory bodies may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- the FDA may require the establishment or modification of Risk Evaluation Mitigation Strategies or a comparable foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of our products and impose burdensome implementation requirements on us;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to subjects or patients;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular planned product, if approved.

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

Alternatives exist for our products and we will likely face competition with respect to any planned products that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies, medical device companies, and biotechnology companies worldwide. These companies may reduce prices for their competing drugs in an effort to gain or retain market share and undermine the value our products might otherwise be able to offer to payers. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Many of these competitors are attempting to develop therapeutics for our target indications.

Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified technical and management personnel, establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our patent rights may prove to be an inadequate barrier to competition.

We are the sole owner of patents and patent applications in the U.S. with claims covering the compounds underlying our primary product candidate, DCCR. Foreign counterparts of these patents and applications have been issued in the E.U., Japan, China, Canada, Australia, India and Hong Kong. However, the lifespan of any one patent is limited, and each of these patents will ultimately expire and we cannot be sure that pending applications will be granted, or that we will discover new inventions which we can successfully patent. Moreover, any of our granted patents may be held invalid by a court of competent jurisdiction, and any of these patents may also be construed narrowly by a court of competent jurisdiction in such a way that it is held to not directly cover DCCR. Furthermore, even if our patents are held to be valid and broadly interpreted, third parties may find legitimate ways to compete with DCCR by inventing around our patent. Finally, the process of obtaining new patents is lengthy and expensive, as is the process for enforcing patent rights against an alleged infringer. Any such litigation could take years, cost large sums of money and pose a significant distraction to management. Indeed, certain jurisdictions outside of the U.S. and E.U., where we hope to initially commercialize DCCR have a history of inconsistent, relatively lax or ineffective enforcement of patent rights. In such jurisdictions, even a valid patent may have limited value. Our failure to effectively prosecute our patents would have a harmful impact on our ability to commercialize DCCR in these jurisdictions.

Even if we are able to maintain our existing partners in commercializing our products, they may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, thereby harming our business.

The regulations that govern marketing approvals, pricing and reimbursement for new products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more planned products, even if our planned products obtain regulatory approval.

Our ability to commercialize our products successfully also will depend in part on the extent to which reimbursement for these products and related treatments becomes available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payers, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with products administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any planned product that we successfully develop.

In the U.S., eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payers and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the U.S. Third-party payers often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies.

Our inability to promptly obtain coverage and profitable payment rates from both government funded and private payers for new products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. In some foreign countries, including major markets in the E.U. and Japan, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take nine to twelve months or longer after the receipt of regulatory marketing approval for a product. 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 product to other available therapies. Our business could be materially harmed if reimbursement of our products, if any, is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the sale of our products. The marketing, sale and use of our products could lead to the filing of product liability claims against us if someone alleges that our tests failed to perform as designed. We may also be subject to liability for a misunderstanding of, or inappropriate reliance upon, the information we provide. If we cannot successfully defend ourselves against claims that our products caused injuries, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any planned products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of patients from clinical studies or cancellation of studies;
- significant costs to defend the related litigation and distraction to our management team;
- substantial monetary awards to patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently hold $8.0 million in product liability insurance coverage, which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

The loss of key members of our executive management team could adversely affect our business.

Our success in implementing our business strategy depends largely on the skills, experience and performance of key members of our executive management team and others in key management positions, including Dr. Anish Bhatnagar, our Chief Executive Officer, James Mackaness, our Chief Financial Officer, Neil M. Cowen, our Senior Vice President of Drug Development, Kristen Yen, our Vice President of Clinical Operations, and Patricia Hirano our Vice President of Regulatory Affairs. The collective efforts of each of these persons, and others working with them as a team, are critical to us as we continue to develop our technologies, tests and research and development and sales programs. As a result of the difficulty in locating qualified new management, the loss or incapacity of existing members of our executive management team could adversely affect our operations. If we were to lose one or more of these key employees, we could experience difficulties in finding qualified successors, competing effectively, developing our technologies and implementing our business strategy. Our officers all have employment agreements; however, the existence of an employment agreement does not guarantee retention of members of our executive management team and we may not be able to retain those individuals for the duration of or beyond the end of their respective terms. We have secured a $1.0 million “key person” life insurance policy on our Chief Executive Officer, Dr. Anish Bhatnagar, but do not otherwise maintain “key person” life insurance on any of our employees.

In addition, we rely on collaborators, consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our collaborators, consultants and advisors are generally employed by employers other than us and may have commitments under agreements with other entities that may limit their availability to us.

Management turnover creates uncertainties and could harm our business

We have experienced changes in our executive leadership in the past. David O'Toole, our Senior Vice President and Chief Financial Officer, resigned from employment effective September 11, 2017. Mr. Jonathan Wolter, a partner at FLG Partners, LLC, was retained as our interim Chief Financial Officer and on May 30, 2018, was appointed Chief Financial Officer. On November 14, 2019, we amended our agreement with FLG Partners LLC, to replace Mr. Jonathan Wolter with Mr. James Mackaness as Chief Financial Officer, after Mr. Wolter accepted a full-time position at another company and was therefore no longer available to continue his engagement with us. Patricia Hirano was appointed Vice President of Regulatory Affairs on January 1, 2019.

Changes to strategic or operating goals, which can often times occur with the appointment of new executives, can create uncertainty, may negatively impact our ability to execute quickly and effectively, and may ultimately be unsuccessful. In addition, executive leadership transition periods are often difficult as the new executives gain detailed knowledge of our operations, and friction can result from changes in strategy and management style. Management turnover inherently causes some loss of institutional knowledge, which can negatively affect strategy and execution. Until we integrate new personnel, and unless they are able to succeed in their positions, we may be unable to successfully manage and grow our business, and our financial condition and profitability may suffer.

Further, to the extent we experience additional management turnover, competition for top management is high and it may take months to find a candidate that meets our requirements. If we are unable to attract and retain qualified management personnel, our business could suffer.

There is a scarcity of experienced professionals in our industry. If we are not able to retain and recruit personnel with the requisite technical skills, we may be unable to successfully execute our business strategy.

The specialized nature of our industry results in an inherent scarcity of experienced personnel in the field. Our future success depends upon our ability to attract and retain highly skilled personnel, including scientific, technical, commercial, business, regulatory and administrative personnel, necessary to support our anticipated growth, develop our business and perform certain contractual obligations. Given the scarcity of professionals with the scientific knowledge that we require and the competition for qualified personnel among biotechnology businesses, we may not succeed in attracting or retaining the personnel we require to continue and grow our operations.

We may acquire other businesses or form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions or licenses of assets or acquisitions of businesses. We also may pursue strategic alliances and joint ventures that leverage our core technology and industry experience to expand our product offerings or sales and distribution resources. Our company has limited experience with acquiring other companies, acquiring or licensing assets or forming strategic alliances and joint ventures. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. Integration of an acquired company also may disrupt ongoing operations and require management resources that would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a material negative effect on our results of operations.

We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, license, strategic alliance or joint venture. To finance such a transaction, we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

International expansion of our business will expose us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the U.S.

Our business strategy contemplates international expansion, including partnering with distributors, and introducing our current products and other planned products outside the U.S. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- potential failure by us or our distributors to obtain regulatory approvals for the sale or use of our current products and our planned future products in various countries;
- difficulties in managing foreign operations;
- complexities associated with managing government payer systems, multiple payer-reimbursement regimes or self-pay systems;
- logistics and regulations associated with shipping products, including infrastructure conditions and transportation delays;
- limits on our ability to penetrate international markets if our distributors do not execute successfully;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable, and exposure to foreign currency exchange rate fluctuations;
- reduced protection for intellectual property rights, or lack of them in certain jurisdictions, forcing more reliance on our trade secrets, if available;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- failure to comply with the Foreign Corrupt Practices Act, including its books and records provisions and its anti-bribery provisions, by maintaining accurate information and control over sales activities and distributors' activities.

Any of these risks, if encountered, could significantly harm our future international expansion and operations and, consequently, have a material adverse effect on our financial condition, results of operations and cash flows.

Intrusions into our computer systems could result in compromise of confidential information.

Any software we develop or use for any of our products may be potentially subject to malfunction or vulnerable to physical break-ins, hackers, improper employee or contractor access, computer viruses, programming errors, or similar problems. Any of these might result in confidential medical, business or other information of other persons or of ourselves being revealed to unauthorized persons.

There are a number of state, federal and international laws protecting the privacy and security of health information and personal data, including on electronic medical systems. As part of the American Recovery and Reinvestment Act 2009, or ARRA, Congress amended the privacy and security provisions of the Health Insurance Portability and Accountability Act of 1996, or HIPAA. HIPAA imposes limitations on the use and disclosure of an individual's protected healthcare information by healthcare providers, healthcare clearinghouses, and health insurance plans, collectively referred to as covered entities. The HIPAA amendments also impose compliance obligations and corresponding penalties for non-compliance on individuals and entities that provide services to healthcare providers and other covered entities, collectively referred to as business associates. ARRA also made significant increases in the penalties for improper use or disclosure of an individual's health information under HIPAA and extended enforcement authority to state attorneys general. The amendments also create notification requirements for individuals whose health information has been inappropriately accessed or disclosed: notification requirements to federal regulators and in some cases, notification to local and national media. Notification is not required under HIPAA if the health information that is improperly used or disclosed is deemed secured in accordance with encryption or other standards developed by HHS. Most states have laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms to ensure ongoing protection of personal information. Activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers or to alleviate problems caused by such breaches.

Risks related to the operation of our business

Any future distribution or commercialization agreements we may enter into for our products may place the development of these products outside our control, may require us to relinquish important rights, or may otherwise be on terms unfavorable to us.

We may enter into additional distribution or commercialization agreements with third parties with respect to our products. Our likely collaborators for any distribution, marketing, licensing or other collaboration arrangements include large and mid-size companies, regional and national companies, and distribution or group purchasing organizations. We will have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our products. Our ability to generate revenue from these arrangements will depend in part on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our products are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to any such collaborations;
- collaborators may not pursue development and commercialization of our products, or may elect not to continue or renew efforts based on clinical study results, changes in their strategic focus for a variety of reasons, potentially including the acquisition of competitive products, availability of funding, and mergers or acquisitions that divert resources or create competing priorities;
- collaborators may delay clinical studies, provide insufficient funding for a clinical study program, stop a clinical study, abandon a product, repeat or conduct new clinical studies or require a new engineering iteration of a product for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our products or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable products; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

Any termination or disruption of collaborations could result in delays in the development of products, increases in our costs to develop the products or the termination of development of a product.

We expect to expand our development, regulatory and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of December 31, 2019, we had twelve employees and thirteen full-time or part-time consultants. Over the next several years, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, quality assurance, engineering, product development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Future growth would impose significant added responsibilities on members of management, including:

- managing our clinical trials effectively, which we anticipate being conducted at numerous clinical sites;
- identifying, recruiting, maintaining, motivating and integrating additional employees with the expertise and experience we will require;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- managing additional relationships with various strategic partners, suppliers and other third parties;
- improving our managerial, development, operational and finance reporting systems and procedures; and
- expanding our facilities.

Our failure to accomplish any of these tasks could prevent us from successfully growing. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Because we intend to commercialize our products outside the U.S., we will be subject to additional risks.

A variety of risks associated with international operations could materially adversely affect our business, including:

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

We rely on third parties to conduct certain components of our clinical studies, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such studies.

We rely on third parties, such as contract research organizations, or CROs, investigational product packaging, labeling and distribution, laboratories, medical institutions and clinical investigators and staff, to perform various functions for our clinical trials. Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. We remain responsible for ensuring that each of our clinical studies is conducted in accordance with the general investigational plan and protocols for the study. Moreover, the FDA requires us and third parties involved in the set-up, conduct, analysis and reporting of the clinical studies to comply with regulations and with standards, commonly referred to as good clinical practices, or GCP, to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of patients in clinical studies are protected. Our clinical investigators are also required to comply with GCPs. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical studies in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our planned products and will not be able to, or may be delayed in our efforts to, successfully commercialize our planned products.

If we use biological and hazardous materials in a manner that causes injury, we could be liable for damages.

Our manufacturing processes currently require the controlled use of potentially harmful chemicals. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject to, on an ongoing basis, federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may become significant and could have a material adverse effect on our financial condition, results of operations and cash flows. In the event of an accident or if we otherwise fail to comply with applicable regulations, we could lose our permits or approvals or be held liable for damages or penalized with fines.

Risks related to intellectual property

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Patent litigation is prevalent in our sectors. Our commercial success depends upon our ability and the ability of our distributors, contract manufacturers, and suppliers to manufacture, market, and sell our planned products, and to use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights or intellectual property of third parties. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology. Third parties may assert infringement claims against us based on existing or future intellectual property rights. If we are found to infringe a third-party's intellectual property rights, we could be required to obtain a license from such third-party to continue developing and marketing our products and technology. We may also elect to enter into such a license in order to settle pending or threatened litigation. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us and could require us to pay significant royalties and other fees.

We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our planned products or force us to cease some of our business operations, which could materially harm our business. Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. These and other claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business to the infringement claims discussed above.

Even if we are successful in defending against intellectual property claims, litigation or other legal proceedings relating to such claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of litigation or other intellectual property related proceedings could have a material adverse effect on our ability to compete in the marketplace.

If we fail to comply with our obligations in our intellectual property agreements, we could lose intellectual property rights that are important to our business.

We are a party to intellectual property arrangements and expect that our future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, any licensor may have the right to terminate such agreements, in which event we may not be able to develop and market any product that is covered by such agreements.

The risks described elsewhere pertaining to our intellectual property rights also apply to any intellectual property rights that we may license, and any failure by us or any future licensor to obtain, maintain, defend and enforce these rights could have a material adverse effect on our business.

Our ability to successfully commercialize our technology and products may be materially adversely affected if we are unable to obtain and maintain effective intellectual property rights for our technologies and planned products, or if the scope of the intellectual property protection is not sufficiently broad.

Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the U.S. and in other countries with respect to our proprietary technology and products.

The patent position of pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unresolved. In recent years patent rights have been the subject of significant litigation. As a result, the issuance, scope, validity, enforceability and commercial value of the patent rights we rely on are highly uncertain. Pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of the patents we rely on or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we or were the first to file for patent protection of such inventions.

Even if the patent applications we rely on issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and the patents we rely on may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new planned products, patents protecting such products might expire before or shortly after such products are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage.

We may become involved in legal proceedings to protect or enforce our intellectual property rights, which could be expensive, time-consuming, or unsuccessful.

Competitors may infringe or otherwise violate the patents we rely on, or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. In addition, in an infringement proceeding, a court may decide that a patent we are asserting is invalid or unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that the patents we are asserting do not cover the technology in question. An adverse result in any litigation proceeding could put one or more patents at risk of being invalidated or interpreted narrowly. 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 this type of litigation.

Interference or derivation proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office, or USPTO, or any foreign patent authority may be necessary to determine the priority of inventions or other matters of inventorship with respect to patents and patent applications. We may become involved in proceedings, including oppositions, interferences, derivation proceedings interparty reviews, patent nullification proceedings, or re-examinations, challenging our patent rights or the patent rights of others, and the outcome of any such proceedings are highly uncertain. An adverse determination in any such proceeding could reduce the scope of, or invalidate, important patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Our business also could be harmed if a prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights. If we are unable to resolve these disputes, we could lose valuable intellectual property rights.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical or management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected, harming our business and competitive position.

In addition to our patented technology and products, we rely upon confidential proprietary information, including trade secrets, unpatented know-how, technology and other proprietary information, to develop and maintain our competitive position. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in the market. We seek to protect our confidential proprietary information, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us. These agreements are designed to protect our proprietary information; however, we cannot be certain that our trade secrets and other confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets, or that technology relevant to our business will not be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees, consultants or collaborators that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could be disclosed, misappropriated or otherwise become known or be independently discovered by our competitors. In addition, intellectual property laws in foreign countries may not protect trade secrets and confidential information to the same extent as the laws of the U.S. If we are unable to prevent disclosure of the intellectual property related to our technologies to third parties, we may not be able to establish or maintain a competitive advantage in our market, which would harm our ability to protect our rights and have a material adverse effect on our business.

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

Filing, prosecuting and defending patents on all of our planned products throughout the world would be prohibitively expensive to us. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as in the U.S. These products may compete with our products in jurisdictions where we do not have any issued patents and our 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 patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make products that are similar to our current and planned products, but that are not covered by claims in our patents;
- The original filers of our patents that we developed or purchased might not have been the first to make the inventions covered by the claims contained in such patents;
- We might not have been the first to file patent applications covering an invention;
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- Pending patent applications may not lead to issued patents;
- Issued patents may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- We may not develop or in-license additional proprietary technologies that are patentable; and
- The patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

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 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 or applications will be due to be paid by us to the United States Patent and Trademark Office, or USPTO, and various governmental patent agencies outside of the U.S. in several stages over the lifetime of the patents or applications. 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. In such an event, our competitors might be able to use our technologies and this circumstance would have a material adverse effect on our business

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of our issued patents.

In March 2013, under the America Invents Act, or AIA, the U.S. moved to a first-to-file system and made certain other changes to its patent laws. The effects of these changes are currently unclear as the USPTO must still implement various regulations, the courts have yet to address these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. Accordingly, it is not yet clear what, if any, impact the AIA will have on the operation of our business. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, all of which could have a material adverse effect on our business and financial condition.

If we do not obtain a patent term extension in the U.S. under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for our planned products, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our products, if any, one or more of the U.S. patents covering any such approved product(s) or the use thereof may be eligible for up to five years of patent term restoration under the Hatch-Waxman Act. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product. Patent term extension also may be available in certain foreign countries upon regulatory approval of our planned products. Nevertheless, we may not be granted patent term extension either in the U.S. or in any foreign country because of, for example, our failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority 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 requested, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

Risks related to government regulation

The regulatory approval process is expensive, time consuming and uncertain, and may prevent us from obtaining approvals for our planned products.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of our products are subject to extensive regulation by the FDA in the U.S. and other regulatory authorities in other countries, which regulations differ from country to country. We are not permitted to market our planned products in the U.S. until we received the requisite approval or clearance from the FDA. We have not submitted an application or received marketing approval for any planned products. Obtaining approvals from the FDA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions, including the following:

- warning letters;
- civil or criminal penalties and fines;
- injunctions;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical studies;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to accept or approve applications for marketing approval of new drugs or biologics or supplements to approved applications filed by us;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of our products or import bans.

Prior to receiving approval to commercialize any of our planned products in the U.S. or abroad, we may be required to demonstrate with substantial evidence from well-controlled clinical studies, and to the satisfaction of the FDA and other regulatory authorities abroad, that such planned products are safe and effective for their intended uses. Results from preclinical studies and clinical studies can be interpreted in different ways. Even if we believe the preclinical or clinical data for our planned products are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering any of our planned products to humans may produce undesirable side effects, which could interrupt, delay or cause suspension of clinical studies of our planned products and result in the FDA or other regulatory authorities denying approval of our planned products for any or all targeted indications.

Regulatory approval from the FDA is not guaranteed, and the approval process is expensive and may take several years. The FDA also has substantial discretion in the approval process. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical studies or perform additional preclinical studies and clinical studies. The number of preclinical studies and clinical studies that will be required for FDA approval varies depending on the planned product, the disease or condition that the planned product is designed to address and the regulations applicable to any particular planned product. The FDA can delay, limit or deny approval of a planned product for many reasons, including, but not limited to, the following:

- a planned product may not be deemed safe or effective;
- FDA officials may not find the data from preclinical studies and clinical studies sufficient;
- the FDA might not approve our or our third-party manufacturer’s processes or facilities; or
- the FDA may change its approval policies or adopt new regulations.

If any planned products fail to demonstrate safety and effectiveness in clinical studies or do not gain regulatory approval, our business and results of operations will be materially and adversely harmed.

The research, development, conduct of clinical trials, manufacturing, labeling, approval, selling, import, export, marketing and distribution of pharmaceutical and biologic products also are subject to extensive regulation by the FDA in the U.S. and other regulatory authorities in other countries, which regulations differ from country to country.

Nonclinical Testing

Before a drug candidate in can be tested in humans, it must be studied in laboratory experiments and in animals to generate data to support the drug candidate's potential benefits and safety. Additional nonclinical testing may be required during the clinical development process such as reproductive toxicology and juvenile toxicology studies. Carcinogenicity studies in two species are generally required for products intended for long-term use.

Investigational New Drug Exemption Application (IND)

The results of initial nonclinical tests, together with manufacturing information, analytical data and a proposed clinical trial protocol and other information, are submitted as part of an IND to the FDA. If FDA does not identify significant issues during the initial 30-day IND review, the drug candidate can then be studied in human clinical trials to determine if the drug candidate is safe and effective. Each clinical trial protocol and/or amendment, new nonclinical data, and/or new or revised manufacturing information must be submitted to the IND, and the FDA has 30 days to complete its review of each submission.

Clinical Trials

These clinical trials involve three separate phases that often overlap, can take many years and are very expensive. These three phases, which are subject to considerable regulation, are as follows:

- Phase I. The drug candidate is given to a small number of healthy human control subjects or patients suffering from the indicated disease, to test for safety, dose tolerance, pharmacokinetics, metabolism, distribution and excretion.
- Phase II. The drug candidate is given to a limited patient population to determine the effect of the drug candidate in treating the disease, the best dose of the drug candidate, and the possible side effects and safety risks of the drug candidate. It is not uncommon for a drug candidate that appears promising in Phase I clinical trials to fail in the more rigorous Phase II clinical trials.
- Phase III. If a drug candidate appears to be effective and safe in Phase II clinical trials, Phase III clinical trials are commenced to confirm those results. Phase III clinical trials are conducted over a longer term, involve a significantly larger population, are conducted at numerous sites in different geographic regions and are carefully designed to provide reliable and conclusive data regarding the safety and benefits of a drug candidate. It is not uncommon for a drug candidate that appears promising in Phase II clinical trials to fail in the more rigorous and extensive Phase III clinical trials.

For each clinical trial, an independent IRB or independent ethics committee, covering each site proposing to conduct a clinical trial must review and approve the plan for any clinical trial and informed consent information for subjects before the trial commences at that site and it must monitor the study until completed. The FDA, the IRB, or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk or for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials involve the administration of an investigational drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Sponsors of clinical trials generally must register and report, at the NIH-maintained website ClinicalTrials.gov, key parameters of certain clinical trials.

At any point in this process, the development of a drug candidate can be stopped for a number of reasons including safety concerns and lack of treatment benefit. We cannot be certain that any clinical trials that we are currently conducting or any that we conduct in the future will be completed successfully or within any specified time period. We may choose, or FDA may require us, to delay or suspend our clinical trials at any time if it appears that the patients are being exposed to an unacceptable health risk or if the drug candidate does not appear to have sufficient treatment benefit.

FDA Approval Process

When we believe that the data from our clinical trials show an adequate level of safety and efficacy, we submit the application to market the drug for a particular use, normally a New Drug Application (NDA) with FDA. FDA may hold a public hearing where an independent advisory committee of expert advisors asks additional questions and makes recommendations regarding the drug candidate. This committee makes a recommendation to FDA that is not binding but is generally followed by FDA. If FDA agrees that the compound has met the required level of safety and efficacy for a particular use, it will allow the drug candidate in the United States to be marketed and sold for that use. It is not unusual, however, for FDA to reject an application because it believes that the risks of the drug candidate outweigh the purported benefit or because it does not believe that the data submitted are reliable or conclusive. The FDA may also issue a Complete Response Letter, or CRL, to indicate that the review cycle for an application is complete and that the application is not ready for approval. CRLs generally outline the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when the deficiencies have been addressed to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

FDA may also require Phase IV non-registrational studies to explore scientific questions to further characterize safety and efficacy during commercial use of our drug. FDA may also require us to provide additional data or information, improve our manufacturing processes, procedures or facilities or may require extensive surveillance to monitor the safety or benefits of our product candidates if it determines that our filing does not contain adequate evidence of the safety and benefits of the drug. In addition, even if FDA approves a drug, it could limit the uses of the drug. FDA can withdraw approvals if it does not believe that we are complying with regulatory standards or if problems are uncovered or occur after approval.

In addition to obtaining FDA approval for each drug, we obtain FDA approval of the manufacturing facilities for companies who manufacture our drugs for us. All of these facilities are subject to periodic inspections by FDA. FDA must also approve foreign establishments that manufacture products to be sold in the United States and these facilities are subject to periodic regulatory inspection.

Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems are identified after the product reaches the market. In addition, the FDA may require post-approval testing, including Phase IV studies, and surveillance programs to monitor the effect of approved products which have been commercialized, and the FDA has the authority to prevent or limit further marketing of a product based on the results of these post-marketing programs. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label, and, even if the FDA approves a product, it may limit the approved indications for use for the product or impose other conditions, including labeling or distribution restrictions or other risk-management mechanisms. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, the sponsor may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require the development of additional data or conduct of additional pre-clinical studies and clinical trials.

Even if we receive marketing approval for a planned product, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements.

Once marketing approval has been obtained, the approved product and its manufacturer are subject to continual review by the FDA or non-U.S. regulatory authorities. Future approvals may contain requirements for potentially costly post-marketing follow-up studies to monitor the safety and effectiveness of the approved product. In addition, we are subject to extensive and ongoing regulatory requirements by the FDA and other regulatory authorities with regard to the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for our products.

In addition, we are required to comply with cGMP regulations regarding the manufacture of our drugs, which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory authorities must approve these manufacturing facilities before they can be used to manufacture drug products, and these facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we or a third party discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturer or us, including requiring withdrawal of the product from the market or suspension of manufacturing.

Once a pharmaceutical product is approved, a product will be subject to pervasive and continuing regulation by the FDA, EMA, and other health authorities, including, among other things, recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and generally require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP or QSR 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 cGMP or QSR compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market, though the FDA must provide an application holder with notice and an opportunity for a hearing in order to withdraw its approval of an application. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates the marketing, labeling, advertising and promotion of drug and device products that are placed on the market. While physicians may prescribe drugs and devices for off label uses, manufacturers may only promote for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses, and a company that is found to have improperly promoted off label uses may be subject to significant liability.

Drugs that treat serious or life-threatening diseases and conditions that are not adequately addressed by existing drugs, and for which the development program is designed to address the unmet medical need, may be designated as fast track and/or breakthrough candidates by FDA and may be eligible for accelerated and priority review.

Drugs that are developed for rare diseases can be designated as Orphan Drugs. In the U.S., the disease or condition has an incidence of less than 200,000 persons and in the E.U. the prevalence of the condition must be not more than 5 in 10,000 persons. In the U.S., orphan-designated drugs are granted up to 7-year market exclusivity. In the E.U., products granted orphan designation are subject to reduced fees for protocol assistance, marketing authorization applications, inspections before authorization, applications for changes to marketing authorizations, and annual fees, access to the centralized authorization procedure, and 10 years of market exclusivity.

Drugs are also subject to extensive regulation outside of the U.S. In the E.U., there is a centralized approval procedure that authorizes marketing of a product in all countries of the E.U. (which includes most major countries in the E.U.). If this centralized approval procedure is not used, approval in one country of the E.U. can be used to obtain approval in another country of the E.U. under one of two simplified application processes: the mutual recognition procedure or the decentralized procedure, both of which rely on the principle of mutual recognition. After receiving regulatory approval through any of the E.U. registration procedures, separate pricing and reimbursement approvals are also required in most countries. The E.U. also has requirements for approval of manufacturing facilities for all products that are approved for sale by the E.U. regulatory authorities.

Failure to obtain marketing approvals in foreign jurisdictions will prevent us from marketing our products internationally.

We intend to seek distribution and marketing partners for our current products outside the U.S. and may market planned products in international markets.

We have had limited interactions with foreign regulatory authorities. The approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Moreover, clinical studies or manufacturing processes conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries or regions, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and even if we file we may not receive necessary approvals to commercialize our products in any market.

Healthcare reform measures could hinder or prevent our planned products' commercial success.

In the U.S., there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that could affect our future revenue and profitability and the future revenue and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, one of the most significant healthcare reform measures in decades, the Patient Protection and Affordable Care Act of 2010, or PPACA, was enacted in 2010. The PPACA contains a number of provisions, including those governing enrollments in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. The PPACA, among other things:

- could result in the imposition of injunctions;
- requires collection of rebates for drugs paid by Medicaid managed care organizations; and
- requires manufacturers to participate in a coverage gap discount program, under which they must agree to offer

- 50% point-of-sale discounts off negotiated prices of applicable branded 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.

While the U.S. Supreme Court upheld the constitutionality of most elements of the PPACA in June 2012, other legal challenges are still pending final adjudication in several jurisdictions. The current presidential administration and Congress may continue to attempt broad sweeping changes to the current health care laws. We face uncertainties that might result from modifications or repeal of any of the provisions of the PPACA, including as a result of current and future executive orders and legislative actions. The impact of those changes on us and potential effect on the medical industry as a whole is currently unknown. Any changes to the PPACA are likely to have an impact on our results of operations, and may have a material adverse effect on our results of operations. We cannot predict what other health care programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the United States may have on our business.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. For example, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals for spending reductions to Congress. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, which triggered the legislation's automatic reduction to several government programs, including aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. In January 2013, former President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which delayed for another two months the budget cuts mandated by the sequestration provisions of the Budget Control Act of 2011. The ATRA, among other things, also reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In March 2013, the President signed an executive order implementing sequestration, and in April 2013, the 2% Medicare reductions went into effect. We cannot predict whether any additional legislative changes will affect our business.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of health care. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of health care may adversely affect:

- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

Further, changes in regulatory requirements and guidance may occur and we may need to amend clinical study protocols to reflect these changes. Amendments may require us to resubmit our clinical study protocols IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical study. In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the Governmental Accounting Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the recall and withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products or require safety surveillance or patient education. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical studies and the drug approval process. Data from clinical studies may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate or suspend clinical studies before completion or require longer or additional clinical studies that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

Given the serious public health risks of high-profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk evaluation and mitigation strategies, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, preapproval of promotional materials and restrictions on direct-to-consumer advertising.

If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payers, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations that may affect our ability to operate include, without limitation:

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;
- 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 federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities like us which provide coding and billing advice to customers;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics and medical supplies to report to the HHS information related to physician payments and other transfers of value and physician ownership and investment interests;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers.

The PPACA, among other things, amends the intent requirement of the Federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the PPACA provides that 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 False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Risks related to ownership of our securities

Our stock price may be volatile, and purchasers of our securities could incur substantial losses.

Our stock price has been and is likely to continue to be volatile. The stock market in general, and the market for biotechnology and medical device companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. During the period from January 1, 2019, through December 31, 2019, the high and low closing prices of our common stock ranged from $2.99 to $1.35. As a result of this volatility, investors may not be able to sell their common stock at or above the purchase price. The market price for our common stock may be influenced by many factors, including the following:

- the results of DESTINY PWS, our ongoing Phase III trial of DCCR in Prader Willi Syndrome;
- our ability to successfully commercialize, and realize significant revenues from sales of our products;
- the success of competitive products or technologies;
- the results of other clinical studies of our products or those of our competitors;
- regulatory or legal developments in the U.S. and other countries, especially changes in laws or regulations applicable to our products;
- introductions and announcements of new products by us, our commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing process or sales and marketing terms;
- variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional products or planned products;
- developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- developments concerning our ability to bring our manufacturing processes to scale in a cost-effective manner;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;

- market conditions in the pharmaceutical and biotechnology sectors;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders;
- general economic, industry and market conditions; and
- the other risks described in this "Risk Factors" section.

These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Future sales of our common stock, or the perception that future sales may occur, may cause the market price of our common stock to decline, even if our business is doing well.

Sales of substantial amounts of our common stock in the public market, or the perception that these sales may occur, could materially and adversely affect the price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. All of our shares of common stock are freely tradable, without restriction, in the public market, except for any shares held by our affiliates.

On December 11, 2017, we entered into a Securities Purchase Agreement with certain purchasers, pursuant to which we sold and issued 8,141,116 immediately separable units at a price per unit of $1.84, for aggregate gross proceeds of $15.0 million. Each unit consisted of one share of our common stock and a warrant to purchase 0.74 shares of our common stock at an exercise price of $2.00 per share, for an aggregate of 8,141,116 shares of common stock and corresponding warrants to purchase an aggregate of 6,024,425 shares of common stock, together the shares of common stock are referred to as the 2017 Resale Shares. We also granted certain registration rights to these stockholders, pursuant to which, among other things, we prepared and filed a registration statement with the SEC to register for resale the 2017 Resale Shares. The registration statement was declared effective in February 2018.

On December 19, 2018, we entered into a Securities Purchase Agreement with certain purchasers, pursuant to which we sold and issued 10,272,375 units at a price per unit of $1.61, for aggregate gross proceeds of $16.5 million. Each unit consisted of one share of our common stock and a warrant to purchase 0.05 shares of our common stock at an exercise price of $2.00 per share, for an aggregate of 10,272,375 shares of common stock and corresponding warrants to purchase an aggregate of 513,617 shares of common stock, together with the shares of common stock are referred to as the 2018 Resale Shares. We also granted certain registration rights to these stockholders, pursuant to which, among other things, we have prepared and filed a registration statement with the SEC to register for resale the 2018 Resale Shares. The registration statement was declared effective in April 2019.

On October 25, 2019, we sold 12,841,667 shares of common stock in an underwritten public offering at a price of $1.20 per share for net proceeds of $14.5 million.

In the future, we may issue additional shares of common stock or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangement or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

Our executive officers, directors and principal stockholders may continue to maintain the ability to control or significantly influence all matters submitted to stockholders for approval and under certain circumstances Abingworth LLP, Vivo Ventures, Oracle Investment Management and Jack W. Schuler and their affiliates may have control over key decision making.

Our executive officers, directors and principal stockholders own a majority of our outstanding common stock. Entities associated with Abingworth LLP, Crabtree Ventures, Nantahala Capital Management, LLC, Oracle Investment Management, Jack W. Schuler and our executive officers, directors and affiliated companies, as of December 31, 2019, own approximately 59 percent of our common stock. As a result, the foregoing group of stockholders are able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders will control the election of directors and the approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

We have incurred and will continue to incur significant increased costs as a result of operating as a public company, and our management has devoted and will be required to continue to devote substantial time to new compliance initiatives.

We have incurred and will continue to incur significant legal, accounting and other expenses as a public company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, the other rules and regulations of the SEC, and the rules and regulations of The NASDAQ Capital Market, or NASDAQ. The expenses of being a public company are material, and compliance with the various reporting and other requirements applicable to public companies requires considerable time and attention of management. For example, the Sarbanes-Oxley Act and the rules of the SEC and national securities exchanges have imposed various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. These rules and regulations will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, these rules and regulations may make it difficult and expensive for us to obtain adequate director and officer liability insurance, and we may be required to accept reduced policy limits on coverage or incur substantial costs to maintain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified personnel to serve on our Board of Directors, our board committees, or as executive officers.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, or Section 404. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge.

If we are not able to comply with the requirements of Section 404 in a timely manner the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources. Our ability to successfully implement our business plan and comply with Section 404 requires us to be able to prepare timely and accurate financial statements. We expect that we will need to continue to improve existing, and implement new operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective. This, in turn, could have an adverse impact on trading prices for our common stock, and could adversely affect our ability to access the capital markets.

Our ability to use our net operating loss carry forwards and certain other tax attributes will be limited.

Our ability to utilize our federal net operating loss, carryforwards and federal tax credit will be limited under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code. The limitations apply if an “ownership change,” as defined by Section 382, occurs. Generally, an ownership change occurs if the percentage of the value of the stock that is owned by one or more direct or indirect “five percent shareholders” increases by more than 50% over their lowest ownership percentage at any time during the applicable testing period (typically three years). During the year ended December 31, 2016, we experienced an “ownership change”, and in the year ended December 31, 2017 our acquisition of Essentialis resulted in an ownership change, of which both changes will limit our ability to utilize our existing and acquired net operating losses and other tax attributes to offset taxable income. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other tax attributes to offset U.S. federal taxable income will be subject to limitations, which could potentially result in increased future tax liability to us.

As our warrant holders exercise their warrants into shares of our common stock, our stockholders will be diluted.

The exercise of some or all of our warrants results in issuance of common stock that dilute the ownership interests of existing stockholders. Any sales of the common stock issuable upon exercise of the warrants could adversely affect prevailing market prices of our common stock.

If holders of our warrants elect to exercise their warrants and sell material amounts of our common stock in the market, such sales could cause the price of our common stock to decline, and the potential for such downward pressure on the price of our common stock may encourage short selling of our common stock by holders of our warrants or other parties.

If there is significant downward pressure on the price of our common stock, it may encourage holders of our warrants, or other parties, to sell shares by means of short sales or otherwise. Short sales involve the sale, usually with a future delivery date, of common stock the seller does not own. Covered short sales are sales made in an amount not greater than the number of shares subject to the short seller’s right to acquire common stock, such as upon exercise of warrants. A holder of warrants may close out any covered short position by exercising all, or a portion, of its warrants, or by purchasing shares in the open market. In determining the source of shares to close out the covered short position, a holder of warrants will likely consider, among other things, the price of common stock available for purchase in the open market as compared to the exercise price of the warrants. The existence of a significant number of short sales generally causes the price of common stock to decline, in part because it indicates that a number of market participants are taking a position that will be profitable only if the price of the common stock declines.

Under certain circumstances we may be required to settle the value of the Series C, 2017 PIPE Warrants and 2018 PIPE Warrants in cash.

If, at any time while the Series C, 2017 PIPE Warrants and 2018 PIPE Warrants, or the Warrants, are outstanding, we enter into a “Fundamental Transaction” (as defined in the Warrants), which includes, but is not limited to, a purchase offer, tender offer or exchange offer, a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or other scheme of arrangement), then each registered holder of outstanding Warrants as at any time prior to the consummation of the Fundamental Transaction, may elect and require us to purchase the Warrants held by such person immediately prior to the consummation of such Fundamental Transaction by making a cash payment in an amount equal to the Black Scholes Value of the remaining unexercised portion of such registered holder’s Warrants.

We might not be able to maintain the listing of our securities on The NASDAQ Capital Market.

We have listed our common stock on NASDAQ. We might not be able to maintain the listing standards of that exchange, which includes requirements that we maintain our shareholders' equity, total value of shares held by unaffiliated shareholders, market capitalization above certain specified levels and minimum bid requirement of $1.00 per common share. We do not expect to become profitable for some time and there is a risk that our shareholders' equity could fall below the $2.5 million level required by NASDAQ. If we do not regain compliance with the minimum bid requirement or our shareholders' equity falls below $2.5 million, it will cause us to fail to conform to the NASDAQ listing requirements on an ongoing basis, which in turn could cause our common stock to cease to trade on the NASDAQ exchange, and be required to move to the Over the Counter Bulletin Board or the "pink sheets" exchange maintained by OTC Markets Group, Inc. The OTC Bulletin Board and the "pink sheets" are generally considered to be markets that are less efficient, and to provide less liquidity in the shares, than the NASDAQ market.

Due to the speculative nature of warrants, there is no guarantee that it will ever be profitable for holders of the warrants to exercise the warrants.

The warrants we have issued and outstanding do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, holders of Series C Warrants may exercise their right to acquire common stock and pay an exercise price of $31.25 per share prior to the expiration of the five-year term on March 4, 2020. Holders of the 2017 PIPE Warrants are entitled to purchase one share of our common stock at an exercise price equal to $2.00 per share prior to at the earlier of (i) December 15, 2020 or (ii) 30 days following positive Phase III results for DCCR tablet in Prader-Willi syndrome. Holders of the 2018 PIPE Warrants are entitled to purchase one share of our common stock at an exercise price equal to $2.00 per share prior to the expiration of the five-year term on December 21, 2023.

Following the amendment of the Series D Common Stock Purchase Warrants, the holders may exercise their right to acquire common stock and pay an amended exercise price of $8.75 per share prior to the expiration of the five-year term on October 15, 2020. In certain circumstances, the Series C Warrants and Series D Warrants may be exercisable on a cashless basis. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the warrants, and, consequently, whether it will ever be profitable for holders of the warrants to exercise the warrants.

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 will depend, 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 our company 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.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions include the following:

- our Board of Directors is divided into three classes with staggered three-year terms which may delay or prevent a change of our management or a change in control;
- our Board of Directors has the right to elect directors to fill a vacancy created by the expansion of our Board of Directors or the resignation, death or removal of a director, which will prevent stockholders from being able to fill vacancies on our Board of Directors;
- our stockholders are not able to act by written consent or call special stockholders' meetings; as a result, a holder, or holders, controlling a majority of our capital stock cannot take certain actions other than at annual stockholders' meetings or special stockholders' meetings called by our Board of Directors, the chairman of our board, the chief executive officer or the president;
- our certificate of incorporation prohibits cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- amendments of our certificate of incorporation and bylaws require the approval of 66 2/3% of our outstanding voting securities;
- our stockholders are required to provide advance notice and additional disclosures in order to nominate individuals for election to our Board of Directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company; and
- our Board of Directors are able to issue, without stockholder approval, shares of undesignated preferred stock, which makes it possible for our Board of Directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our employment agreements with our executive officers may require us to pay severance benefits to any of those persons who are terminated in connection with a change in control of us, which could harm our financial condition or results.

Certain of our executive officers are parties to employment agreements that contain change in control and severance provisions providing for aggregate cash payments for severance and other benefits and acceleration of stock options vesting in the event of a termination of employment in connection with a change in control of us. The accelerated vesting of options could result in dilution to our existing stockholders and harm the market price of our common stock. The payment of these severance benefits could harm our financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be our stockholders' sole source of gain.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of existing or any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

Facilities

Our principal facilities consist of office space in Redwood City, California. We currently occupy 6,368 square feet of office space under a non-cancelable operating lease that terminates in May 2021.

We believe that the facilities that we currently lease are adequate for our needs for the immediate future and that, should it be needed, additional space can be leased on commercially reasonable terms to accommodate any future growth.

ITEM 3. LEGAL PROCEEDINGS

We may, from time to time, be party to litigation and subject to claims that arise in the ordinary course of business. In addition, third parties may, from time to time, assert claims against us in the form of letters and other communications. We currently believe that these ordinary course matters will not have a material adverse effect on our business; however, the results of litigation and claims are inherently unpredictable. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

Our common stock is quoted on NASDAQ under the symbol "SLNO". Our Series C Warrants, Series D Warrants, 2017 PIPE Warrants and 2018 PIPE Warrants are not traded on a national securities exchange.

As of February 28, 2020, there were 56 shareholders of record for our common stock. A substantially greater number of stockholders may be "street name" or beneficial holders, whose shares are held of record by banks, brokers and other financial institutions.

Dividend Policy

We have never declared or paid cash dividends on our common stock, and currently do not plan to declare dividends on shares of our common stock in the foreseeable future. We expect to retain our future earnings, if any, for use in the operation and expansion of our business. The payment of cash dividends in the future, if any, will be at the discretion of our board of directors and will depend upon such factors as earnings levels, capital requirements, our overall financial condition and any other factors deemed relevant by our board of directors.

Unregistered Sales of Equity Securities and Use of Proceeds

(a) Recent Sales of Unregistered Equity Securities

- On December 19, 2018, we entered into a Securities Purchase Agreement with certain purchasers, pursuant to which we sold and issued 10,272,375 units at a price per unit of $1.61, for aggregate gross proceeds of $16.5 million and net proceeds of $16.3 million. Each unit consisted of one share of our common stock and a warrant to purchase 0.05 shares of our common stock at an exercise price of $2.00 per share, for an aggregate of 10,272,375 shares of common stock and corresponding warrants to purchase an aggregate of 513,617 shares of common stock, together with the shares of common stock are referred to as the 2018 Resale Shares. We also granted certain registration rights to these stockholders, pursuant to which, among other things, we prepared and filed a registration statement with the SEC to register for resale the 2018 Resale Shares. The registration statement was declared effective in April 2019.
- On December 11, 2017, we entered into a Securities Purchase Agreement with certain purchasers, pursuant to which we sold and issued 8,141,116 immediately separable units at a price per unit of $1.84, for aggregate gross proceeds of $15.0 million and net proceeds of $13.8 million. Each unit consisted of one share of our common stock and a warrant to purchase 0.74 shares of our common stock at an exercise price of $2.00 per share, for an aggregate of 8,141,116 shares of common stock and corresponding warrants to purchase an aggregate of 6,024,425 shares of common stock, together the shares of common stock are referred to as the 2017 Resale Shares. We also granted certain registration rights to these stockholders, pursuant to which, among other things, we prepared and filed a registration statement with the SEC to register for resale the 2017 Resale Shares. The registration statement was declared effective in February 2018.

Except as outlined above, none of the foregoing transactions involved any underwriters, underwriting discounts or commissions or any public offering. We believe that these transactions were exempt from the registration requirements of the Securities Act under Section 4(2) of the Securities Act as transactions by an issuer not involving any public offering. The recipients of securities in each of these transactions represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the stock certificates and instruments issued in such transactions. All recipients had adequate access, through their relationships with us, to information about us.

(b) Use of Proceeds

There has been no material change in the planned use of proceeds from the 2017 PIPE Offering or 2018 PIPE Offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) for such transaction.

ITEM 6. SELECTED FINANCIAL INFORMATION

Pursuant to Item 301(c) of Regulation S-K as a smaller reporting company, we are not required to provide the information required by this item.

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

The following discussion and analysis should be read in conjunction with our audited consolidated financial statements and the related notes that appear elsewhere in this Annual Report on Form 10-K. This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "estimate," "plan," or "continue," and similar expressions or variations. Such forward-looking statements are subject to risks, uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section titled "Risk Factors," set forth in Part I, Item 1A of this Annual Report on Form 10-K and elsewhere in this report. The forward-looking statements in this Annual Report on Form 10-K represent our views as of the date of this Annual Report on Form 10-K. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

Business Overview

We are focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. Our lead candidate, Diazoxide Choline Controlled Release tablits, or DCCR, a once-daily oral tablet for the treatment of Prader-Willi Syndrome, or PWC, is currently being evaluated in a Phase III clinical development program.

We initially established our operations as a diversified healthcare company that developed and commercialized innovative diagnostics, devices and therapeutics addressing unmet medical needs, which consisted of: precision metering of gas flow technology marketed as Serenz ® Allergy Relief, or Serenz; CoSense ® End-Tidal Carbon Monoxide (ETCO) Monitor, or CoSense, which measures ETCO and aids in the detection of excessive hemolysis, a condition in which red blood cells degrade rapidly and which can lead to adverse neurological outcomes; and, products that included temperature probes, scales, surgical tables, and patient surfaces.

On March 7, 2017, we completed a merger, or the Merger, with Essentialis. Essentialis's efforts prior to the Merger were focused primarily on developing and testing product candidates that target the ATP-sensitive potassium channel, a metabolically-regulated membrane protein whose modulation has the potential to impact a wide range of rare metabolic, cardiovascular, and CNS diseases. Essentialis had tested DCCR as a treatment for PWS, a complex metabolic/neurobehavioral disorder. DCCR has orphan designation for the treatment of PWS in the United States, or U.S., as well as in the European Union, or E.U.

Subsequent to the Merger with Essentialis described above, we determined to divest, sell or otherwise dispose of its business efforts focused on the development and commercialization of its Serenz and CoSense technologies. Accordingly, and pursuant to ASC 205-20-45-10, the assets and liabilities related to the discontinued activities of CoSense and Serenz were presented separately in the balance sheet as held for sale items, and the related operations reported herein for the CoSense and Serenz activities are reported as discontinued operations in the statements of operations.

On December 4, 2017, we and our then wholly-owned subsidiary Capnia, entered into a joint venture with OptAsia Healthcare Limited, or OAHL, with the purpose of developing and commercializing CoSense with the intent to transfer ownership of Capnia to OAHL. During October 2018, Capnia issued 1,690,322 shares of its common stock to OAHL, representing 53% of its outstanding shares, after which we no longer held a controlling interest in Capnia. Accordingly, we deconsolidated Capnia's financial statements from ours and our remaining minority interest in Capnia was reported as a Minority interest investment in our consolidated balance sheet. During September 2019, the Company sold its remaining 47% investment in Capnia to Sinon Investments LLC, or Sinon. Following the transaction, the Company has no interest remaining in Capnia and the previous joint venture agreement with OAHL has been terminated.

On July 30, 2018, the FDA has granted Fast Track designation to DCCR for the treatment of PWS. We are currently conducting a Phase III clinical trial of DCCR for the treatment of PWS.

As of December 31, 2019, we had an accumulated deficit of $157.8 million, primarily as a result of research and development and general and administrative expenses. We may never be successful in commercializing our novel therapeutic-lead candidate DCCR. Accordingly, we expect to incur significant losses from operations for the foreseeable future, and there can be no assurance that we will ever generate significant revenue or profits.

Recent Financings

2017 PIPE Offering

On December 11, 2017, we entered into a Securities Purchase Agreement with certain purchasers, pursuant to which we sold and issued 8,141,116 immediately separable units at a price per unit of $1.84, for aggregate gross proceeds of $15.0 million. Each unit consisted of one share of our common stock and a warrant to purchase 0.74 shares of our common stock at an exercise price of $2.00 per share, for an aggregate of 8,141,116 shares of common stock and corresponding warrants to purchase an aggregate of 6,024,425 shares of common stock, together the shares of common stock are referred to as the 2017 Resale Shares. We also granted certain registration rights to these stockholders, pursuant to which, among other things, we prepared and filed a registration statement with the SEC to register for resale the 2017 Resale Shares. The registration statement was declared effective in February 2018.

2018 PIPE Offering

On December 19, 2018, we entered into a Securities Purchase Agreement with certain purchasers, pursuant to which we sold and issued 10,272,375 units at a price per unit of $1.61, for aggregate gross proceeds of $16.5 million. Each unit consisted of one share of our common stock and a warrant to purchase 0.05 shares of our common stock at an exercise price of $2.00 per share, for an aggregate of 10,272,375 shares of common stock and corresponding warrants to purchase an aggregate of 513,617 shares of common stock, together with the shares of common stock are referred to as the 2018 Resale Shares. We also granted certain registration rights to these stockholders, pursuant to which, among other things, we prepared and filed a registration statement with the SEC to register for resale the 2018 Resale Shares. The registration statement was declared effective in April 2019.

2019 Public Offering

On October 25, 2019, we sold 12,841,667 shares of common stock in an underwritten public offering at a price of $1.20 per share for net proceeds of $14.5 million.

Financial overview

Summary

We have not generated net income from operations to date, and at December 31, 2019 we had an accumulated deficit of $157.8 million, primarily as a result of research and development and general and administrative expenses. We may never be successful in commercializing our novel therapeutics products for the treatment of rare diseases.

Accordingly, we expect to incur significant losses from operations for the foreseeable future, and there can be no assurance that we will ever generate significant revenue or profits.

Revenue recognition

To date, we have earned no revenue from the commercial development and sale of novel therapeutic products and the revenue resulting from commercialization and sale of the CoSense and Serenz products is reported in discontinued operations.

Research and development expenses

Research and development costs are expensed as incurred. Research and development costs consist primarily of salaries and benefits, professional consultant fees, prototype expenses, certain facility costs and other costs associated with clinical trials, net of reimbursed amounts. Costs to acquire technologies to be used in research and development that have not reached technological feasibility, and have no alternative future use, are expensed to research and development costs when incurred. Research and development expenses resulting from the development of novel therapeutic products are reported in continuing operations, and research and development expenses resulting from the development of the CoSense and Serenz products are reported in discontinued operations.

Sales and marketing expenses

Sales and marketing expenses consist principally of salaries and benefits, professional consulting fees, and other expenses associated with commercial activities. We anticipate these expenses will increase significantly in future periods, reflecting the increased level of sales and marketing activity necessary for the commercial launch of a successful future therapeutic drug candidate. We have to date incurred no sales and marketing expenses related to the sale and commercialization of novel therapeutic products, and the sales and marketing expenses related to the CoSense and Serenz products are reported in discontinued operations.

General and administrative expenses

General and administrative expenses consist principally of salaries and benefits, professional fees for legal, consulting, audit and tax services, insurance, rent, and other general operating expenses not otherwise included in research and development. We anticipate general and administrative expenses will increase in future periods, reflecting an expanding infrastructure, other administrative expenses and increased professional fees associated with being a public reporting company. General and administrative expenses incurred in operating all components of our business are classified as continuing operations and are not allocated to specific research and development or sales and marketing activities that have been discontinued. General and administrative expenses, such as rent, that are incurred specifically to directly support research and development and sales and marketing activities for the CoSense and Serenz products are reported in discontinued operations.

Change in fair value of contingent consideration

Change in fair value of contingent consideration represents the change in the fair value of the additional consideration that we expect to pay Essentialis stockholders based on our assessment of the expected likelihood of achieving commercial sales milestones of $100.0 million and $200.0 million in future years.

Other income (expense)

Other income (expense) is primarily comprised of the gain recognized from the transfer of the majority ownership and resulting deconsolidation of Capnia, the loss from recording our minority interest investment in Capnia after the deconsolidation, and changes in the fair value of the 2017 and 2018 PIPE common stock warrant liabilities.

Critical Accounting Policies and Significant Judgments and Estimates

Our management’s discussion and analysis of financial condition and results of operations are based upon our audited financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an on-going basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable in the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions. Our significant accounting policies are more fully described in Note 3 to our audited financial statements contained herein.

Series A, Series C, 2017 PIPE Warrants, and the 2018 PIPE Warrants

We account for the Series A, Series C, 2017 PIPE warrants, and 2018 PIPE warrants, collectively referred to as the Warrants, in accordance with the guidance in ASC 815 *Derivatives and Hedging*. The Warrants contain standard anti-dilution provisions for stock dividends, stock splits, subdivisions, combinations and similar types of recapitalization events. The Warrants also contain a fundamental transactions provision that permits their settlement in cash at fair value at the option of the holder upon the occurrence of a change in control. Such change in control events include tender offers or hostile takeovers, which are not within our sole control as the issuer of these warrants. Accordingly, the warrants are considered to have a cash settlement feature that precludes their classification as equity instruments. Settlement at fair value upon the occurrence of a fundamental transaction would be computed using the Black Scholes Option Pricing Model, which approximates the binomial lattice model.

We classified the Warrants as liabilities at their fair value and re-measure the warrants at each balance sheet date until they are exercised or expire. Any change in the fair value is recognized as other income (expense) in the statements of operations. The Series A warrants expired in November 2019.

Research and development expense

Research and development costs are charged to operations as incurred. Research and development costs consist primarily of salaries and benefits, consultant fees, prototype expenses, certain facility costs and other costs associated with clinical trials, net of reimbursed amounts.

Costs to acquire technologies to be used in research and development that have not reached technological feasibility and have no alternative future use are expensed to research and development costs when incurred.
Certain Research and Development expenses are reported as Discontinued Operations.

Stock-based compensation expense

Stock-based compensation costs related to stock options and restricted stock units granted to employees, nonemployees and directors are measured at the date of grant based on the estimated fair value of the award. For restricted stock units this fair value is based on our common stock price on the grant date. We estimate the grant date fair value of stock options, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. The grant date fair value of stock-based awards is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the award. Stock options generally vest over four years.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions to estimate the fair value of stock-based awards. If we had made different assumptions, our stock-based compensation expense, net loss and net loss per share of common stock could have been significantly different. These assumptions include:

- *Expected volatility:* We calculate the estimated volatility rate based on the volatility of our common stock together with comparable companies in our industry.
- *Expected term:* We do not believe we are able to rely on our historical exercise and post-vesting termination activity to provide accurate data for estimating the expected term for use in estimating the fair value-based measurement of our options. Therefore, we have opted to use the “simplified method” for estimating the expected term of options.

- *Risk-free rate:* The risk-free interest rate is based on the yields of U.S. Treasury securities with maturities similar to the expected time to liquidity.
- *Expected dividend yield:* We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. Consequently, we used an expected dividend yield of zero.

Contingent consideration

Contingent consideration elements of a business combination are recorded in accordance with ASC 805 which provides that, when contingent consideration terms provide for future payment obligations, the obligation is measured at its fair value on the acquisition date, and the subsequent increase or decrease of the value of the estimated amounts of contingent consideration to be paid is be recognized as expense or income, respectively, in the statements of operations.

Our agreement to pay the selling shareholders of Essentialis for achieving certain commercial milestones resulted in the recognition of a contingent consideration, which was recorded at the inception of the transaction, and subsequent changes to estimate of the amounts of contingent consideration to be paid will be recognized as expenses or income in the statements of operations. The fair value of the contingent consideration is based on our analysis of the likelihood of the drug indication moving from Phase II through approval in the Federal Drug Administration approval process and then reaching the cumulative revenue milestones.

Common Stock Purchase Warrants and Other Derivative Financial Instruments

We account for the warrants in accordance with the guidance in ASC 815 *Derivatives and Hedging*. We classify common stock purchase warrants and other free standing derivative financial instruments as equity if the contracts (i) require physical settlement or net-share settlement or (ii) give us a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). We classify any contracts that (i) require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside our control), (ii) give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement), or (iii) contain reset provisions as either an asset or a liability. We assess classification of freestanding derivatives at each reporting date to determine whether a change in classification between equity and liabilities is required. We determined that certain freestanding derivatives, which principally consist of Series A, Series C, the 2017 PIPE Warrants and 2018 PIPE Warrants, do not satisfy the criteria for classification as equity instruments due to the existence of certain cash settlement features that are not within our sole control or variable settlement provision that cause them to not be indexed to our stock. Our Series A Warrants expired during November 2019.

Income Taxes

We use the liability method of accounting for income taxes, whereby deferred tax assets or liability account balances are calculated at the balance sheet date using current tax laws and rates in effect for the year in which the differences are expected to affect taxable income. We have provided a valuation allowance to reduce deferred tax assets to the amount that will more likely than not be realized.

We make certain estimates and judgments in determining income tax expense for financial statement purposes. These estimates and judgments occur in the calculation of tax credits, benefits and deductions and in the calculation of certain tax assets and liabilities, which arise from differences in the timing of recognition of revenues and expenses for tax and financial statement purposes. Significant changes to these estimates may result in an increase or decrease to our tax provision in a subsequent period.

We make estimates and judgments about our future taxable income that are based on assumptions that are consistent with our plans and estimates. Should the actual amounts differ from our estimates, the amount of our valuation allowance could be materially impacted. Any adjustment to the deferred tax asset valuation allowance would be recorded in the income statement for the periods in which the adjustment is determined to be required.

We account for uncertainty in income taxes as required by the provisions of ASC Topic 740, *Income Taxes*, which clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to estimate and measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement. It is inherently difficult and subjective to estimate such amounts, as this requires us to determine the probability of various possible outcomes. We consider many factors when evaluating and estimating our tax positions and tax benefits, which may require periodic adjustments and may not accurately anticipate actual outcomes.

In addition, the use of net operating loss and tax credit carryforwards may be limited under Section 382 of the Internal Revenue Code in certain situations where changes occur in the stock ownership of a company. In the event that we have had a change in ownership, utilization of the carryforwards could be restricted. For more information, see the section titled "Risk Factors—Our ability to use our net operating loss carry forwards and certain other tax attributes will be limited."

Continuing operations are reported net of the related tax effects and discontinued operations are reported net of related tax effects in the statements of operations.

Results of Continuing Operations

Comparison of the Years Ended December 31, 2019 and 2018 from continuing operations

	Year Ended December 31,		Increase (decrease)	
	2019	2018	Amount	Percentage
	(in thousands)			
Operating expenses:				
Research and development	$ 16,267	$ 7,178	$ 9,089	127%
General and administrative	6,930	6,556	374	6%
Change in fair value of contingent consideration	289	567	(278)	49%
Total operating expenses	23,486	14,301	9,185	64%
Operating loss	(23,486)	(14,301)	(9,185)	64%
Other (expense) income				
Change in fair value of warrants liabilities	(6,964)	522	(7,486)	1434%
Gain on deconsolidation of former subsidiary	—	1,994	(1,994)	100%
Loss from minority interest investment	(478)	(160)	(318)	199%
Interest and other income	154	104	50	48%
Total other (expense) income	(7,288)	2,460	(9,748)	396%
Loss from continuing operations	(30,774)	(11,841)	(18,933)	160%
Loss from discontinued operations	—	(1,494)	1,494	100%
Net loss	$ (30,774)	$ (13,335)	$ (17,439)	131%

Revenue

We have not commenced commercialization of DCCR, our current sole novel therapeutic product, and accordingly, through December 31, 2019, have generated no revenue in continuing operations.

Research and development expense

Research and development expense of $16.3 million for the year ended December 31, 2019 increased by $9.1 million over 2018 resulting primarily from the initiation of the Phase III clinical trial in May 2018. As of December 31, 2019, we have 29 clinical trial sites initiated compared to 13 as of December 31, 2018. As a result, we have incurred increased clinical site costs, consulting costs, lab costs, and manufacturing costs for DCCR production. The company announced the completion of target enrollment in DESTINY PWS, the ongoing Phase III trial of DCCR in Prader Willi Syndrome in January 2020.

General and administrative expense

General and administrative expense of $6.9 million during 2019 increased by approximately $374,000 from 2018. The slight increase was due to a general increase in the level of operations during the year and primarily consisted of an increase in personnel related costs.

Change in fair value of contingent consideration

We are obligated to make cash payments of up to a maximum of $30 million to Essentialis stockholders upon the achievement of certain future commercial milestones associated with the sale of Essentialis' product in accordance with the terms of the Essentialis merger agreement. The fair value of the liability for the contingent consideration payable by us achieving the commercial sales milestones of $100 million and $200 million was estimated to be $5.9 million as of December 31, 2019, an approximate $289,000 increase from the estimate as of December 31, 2018. During 2018 the estimate increased approximately $567,000 from the liability of $5.1 million estimated at December 31, 2017.

Other (expense) income

Other expense of approximately $7.3 million in 2019 increased $9.7 million from other income of $2.5 million during 2018. The increase in other (expense) income was primarily due to a net increase in the fair value of warrant liabilities during 2019 compared to a net decrease in 2018, resulting in a net increase of $7.5 million recognized in other (expense) income. In addition there was a $2.0 million gain recognized during 2018 on the deconsolidation of Capnia upon the issuance of majority shares to OAHL, and an approximately $318,000 higher loss from our minority interest investment in Capnia during 2019 compared to 2018. The loss recorded on our minority interest investment in Capnia during 2019 includes approximately $511,000 for our share of Capnia's net losses during the period, partially offset by a gain of approximately $33,000 recognized upon the sale of the investment. These increases were partially offset by an increase in interest and other income of $50,000.

Results of Discontinued Operations

Discontinued operations during 2018 consist of our activities previously dedicated to the development and commercialization of innovative diagnostics, devices and therapeutics addressing unmet medical needs, which consisted of: precision metering of gas flow technology marketed as Serenz® Allergy Relief, or Serenz; CoSense® End-Tidal Carbon Monoxide (ETCO) Monitor, or CoSense, which measures ETCO and aids in the detection of excessive hemolysis, a condition in which red blood cells degrade rapidly; and products that included temperature probes, scales, surgical tables and patient surfaces. In March 2017, we determined to divest, sell or otherwise dispose of the CoSense, Neo Force, Inc., and Serenz businesses in order to focus on the development and commercialization of novel therapeutics for the treatment of rare diseases. The discontinued operations for the development and commercialization of innovative diagnostic devices and therapeutics are summarized below.

	Year Ended December 31, 2018
Product revenue	$ 62
Cost of product revenue	32
Gross profit	30
Expenses:	
Research and development	1,106
Sales and marketing	25
General and administrative	393
Total expenses	1,524
Operating loss	(1,494)
Net loss from discontinued operations	$ (1,494)

All discontinued operations activity during 2018 related to Capnia and its CoSense products. During October 2018, Capnia issued 53% of its outstanding shares of common stock to OAHL, leaving us with a noncontrolling interest. Accordingly, we deconsolidated Capnia's financial statements from ours and our remaining minority interest in Capnia was reported as a minority interest investment in our condensed consolidated balance sheet. During September 2019, the Company sold its remaining 47% investment in Capnia to Sinon. As Capnia is no longer a consolidated entity of ours, there is no corresponding discontinued operations activity during 2019.

Liquidity and Capital Resources

We had a net loss of $30.8 million during 2019 and an accumulated deficit of $157.8 million at December 31, 2019 from having incurred losses since our inception. We had $16.2 million of working capital at December 31, 2019 and used $17.4 million of cash in operating activities during 2019. We have financed our operations principally through issuances of equity securities. On October 25, 2019, we sold 12,841,667 shares of common stock in an underwritten public offering at a price of $1.20 per share for net proceeds of $14.5 million.

We expect to continue incurring losses for the foreseeable future and will be required to raise additional capital to complete our clinical trials, pursue product development initiatives and penetrate markets for the sale of our products. We believe that we will continue to have access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations or other means, but the access to such capital resources is uncertain and is not assured. If we are unable to secure additional capital, we may be required to curtail our clinical trials and development of new products and take additional measures to reduce costs in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. These measures could cause significant delays in our efforts to complete clinical trials and commercialize our products, which is critical to the realization of our business plan and our future operations. These matters raise substantial doubt about our ability to continue as a going concern within one year from the date of filing this annual report.

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

Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below:

	Year Ended December 31, 2019	Year Ended December 31, 2018
	(in thousands)	
Net cash used in continuing operating activities	$ (17,375)	$ (10,322)
Net cash used in discontinued operating activities	—	(1,361)
Net cash used in operating activities	(17,375)	(11,683)
Net cash provided by (used) in continuing investing activities	528	(8)
Net cash used in discontinued investing activities	—	(172)
Net cash provided by (used in) investing activities	528	(180)
Net cash provided by continuing financing activities	14,481	16,302
Net cash provided by discontinued financing activities	—	1,525
Net cash provided by financing activities	14,481	17,827
Net increase (decrease) in cash and cash equivalents		
Continuing operations	(2,366)	5,972
Discontinued operations	—	(8)
Net increase in cash and cash equivalents	$ (2,366)	$ 5,964

Continuing Operations

Cash used in operating activities

During 2019 operating activities used net cash of $17.4 million, which was primarily due to the loss from continuing operations of $30.8 million, adjusted for non-cash expense of $2.0 million for depreciation and amortization, $7.3 million for the change in fair value of common stock warrants and contingent consideration, approximately $825,000 of expense paid with common stock or equity awards, approximately $386,000 for non-cash lease expense, and an approximate $478,000 operating loss on minority interest investment. Additionally, the usage of cash during 2019 was reduced by $2.5 million due to changes in operating assets and liabilities.

During 2018 operating activities used net cash of $10.3 million, which was primarily due to the loss from continuing operations of $11.8 million, adjusted for non-cash expenses of $2.0 million for depreciation and amortization, $1.3 million of expenses paid with common stock or equity awards, approximately $160,000 operating loss on minority interest investment and approximately $45,000 for the net change in fair value of common stock warrants and contingent consideration, all of which were partially offset by the non-cash gain of $2.0 million recognized on the deconsolidation of Capnia upon the issuance of majority shares to OAHL.

Cash used in investing activities

During 2019 investing activities related to continuing operations provided cash of approximately $528,000, primarily a result of the $500,000 that we received for the sale of our 47% investment in Capnia to Sinon in September 2019 and a security deposit of approximately $108,000 received at the expiration of our facility operating leases that expired in August 2019. This cash inflow was partially offset by cash that was used for a deposit of approximately $59,000 related to the new lease that we entered into in July 2019 for 6,368 square feet of new space in Redwood City, California. There was minimal cash used during 2019 and 2018 for the costs of acquiring property and equipment.

Cash provided by financing activities

During 2019, we obtained $14.5 million of cash from the sale of common stock in a public offering, net of underwriting discounts and other offering expenses. During 2018, we obtained $16.3 million of cash from the issuance of common stock and warrants in the 2018 PIPE offering, net of issuance related costs.

As of December 31, 2019, we had cash and cash equivalents of $20.7 million.

We believe that we do not have sufficient capital resources to sustain operations through at least the next twelve months from the date of this filing. We expect to continue incurring losses for the foreseeable future and will be required to raise additional capital to pursue our therapeutic product development initiatives. These conditions raise substantial doubt about our ability to continue as a going concern for a period of one year from the date of this report.

Discontinued Operations

Cash used in operating activities

There were no discontinued operations during 2019. During 2018, we used net cash of $1.4 million for discontinued operating activities. This usage was primarily a result of the $1.5 million net loss for discontinued operations, partially offset by the change in working capital balances during the year and non-cash depreciation expense.

Cash used in investing activities

There were no investing activities related to discontinued operations during 2019. During 2018, we used approximately $172,000 of cash for discontinued investing activities, representing the net cash reduction for the deconsolidation of Capnia, Inc. upon the transfer of the majority share ownership in October 2018.

Cash provided by financing activities

There were no financing activities related to discontinued operations during 2019. Net cash provided by financing activities related to discontinued operations was $1.5 million during 2018, representing the cash received from our joint venture partner.

Contractual Obligations and Commitments

As of December 31, 2019, we had lease obligations totaling approximately $506,000, consisting of an operating lease for office space in Redwood City, California, and a finance lease for office furniture.

The following table summarizes our contractual obligations as of December 31, 2019 (in thousands).

	Payments due by period				
	Less than 1 year	1 to 3 years	4 to 5 years	After 5 years	Total
Lease obligations	$ 355	$ 151	$ —	$ —	$ 506
Total	$ 355	$ 151	$ —	$ —	$ 506

We are obligated to make future payments to third parties under in-license agreements, including sublicense fees, royalties, and payments that become due and payable on the achievement of certain development and commercialization milestones. As the amount and timing of sublicense fees and the achievement and timing of these milestones are not probable and estimable, such commitments have not been included on our balance sheet or in the contractual obligations tables above. We are also obligated to make certain payments of deferred compensation to management upon completion of certain types of transactions. As the amount and timing of such payments are not probable and estimable, such commitments have not been included on our balance sheet or in the contractual obligations tables above.

Off-Balance Sheet Arrangements

As of December 31, 2019, we had no off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K as promulgated by the SEC.

Accounting Guidance Update

Recently Issued Accounting Guidance

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies and adopted by us as of the specified effective date (see Note 3).

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Sensitivity

We had unrestricted cash and cash equivalents totaling $20.7 million at December 31, 2019. This balance was invested primarily in money market funds and are held for working capital purposes. We do not enter into investments for trading or speculative purposes. We believe we do not have material exposure to changes in fair value as a result of changes in interest rates. Declines in interest rates, however, will reduce future investment income.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Soleno Therapeutics, Inc.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of
Soleno Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Soleno Therapeutics, Inc. (the “Company”) as of December 31, 2019 and 2018, the related consolidated statements of operations, stockholders’ equity, and cash flows for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company’s ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ Marcum LLP

Marcum LLP

We have served as the Company’s auditor since 2014**.**

San Francisco, CA
March 4, 2020

Soleno Therapeutics, Inc.
Consolidated Balance Sheets
(in thousands except share and per share data)

	December 31, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 20,733	$ 23,099
Prepaid expenses and other current assets	411	529
Due from related party	—	64
Minority interest investment in former subsidiary	—	978
Total current assets	21,144	24,670
Long-term assets		
Property and equipment, net	22	12
Operating lease right-of-use assets	398	—
Finance lease right-of-use assets	24	—
Intangible assets, net	16,525	18,469
Other long-term assets	59	—
Total assets	$ 38,172	$ 43,151
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 1,995	$ 934
Accrued compensation	283	274
Accrued clinical trial site costs	1,999	320
Operating lease liabilities	305	—
Other current liabilities	382	349
Total current liabilities	4,964	1,877
Long-term liabilities		
Series A warrant liability	—	49
2017 PIPE Warrant liability	10,822	4,563
2018 PIPE Warrant liability	1,354	600
Contingent liability for Essentialis purchase price	5,938	5,649
Other long-term liabilities	147	—
Total liabilities	23,225	12,738
Commitments and contingencies (Note 8)		
Stockholders' equity		
Preferred Stock, $.001 par value, 10,000,000 shares authorized:		
Series B convertible preferred stock, 13,780 shares designated at December 31, 2019 and December 31, 2018; zero shares issued and outstanding at December 31, 2019 and at December 31, 2018. Liquidation value of zero.	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized, 44,658,054 and 31,755,169 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively.	45	32
Additional paid-in-capital	172,708	157,413
Accumulated deficit	(157,806)	(127,032)
Total stockholders' equity	14,947	30,413
Total liabilities and stockholders' equity	$ 38,172	$ 43,151

See accompanying notes to consolidated financial statements

Soleno Therapeutics, Inc.
Consolidated Statements of Operations
(in thousands except share and per share data)

	For the Years Ended December 31, 2019	2018
Operating expenses		
Research and development	$ 16,267	$ 7,178
General and administrative	6,930	6,556
Change in fair value of contingent consideration	289	567
Total operating expenses	23,486	14,301
Operating loss	(23,486)	(14,301)
Other (expense) income		
Change in fair value of warrants liabilities	(6,964)	522
Gain on deconsolidation of former subsidiary	—	1,994
Loss from minority interest investment	(478)	(160)
Interest and other income	154	104
Total other (expense) income	(7,288)	2,460
Loss from continuing operations	(30,774)	(11,841)
Loss from discontinued operations	—	(1,494)
Net loss	$ (30,774)	$ (13,335)
Loss per common share from continuing operations, basic and diluted	$ (0.90)	$ (0.56)
Loss per common share from discontinued operations, basic and diluted	—	(0.07)
Net loss per common share, basic and diluted	$ (0.90)	$ (0.64)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	34,142,478	20,975,479

See accompanying notes to consolidated financial statements.

Soleno Therapeutics, Inc.
Consolidated Statements of Stockholders' Equity
(in thousands except share data)

	Series B Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balances at January 1, 2018	4,571	$ —	19,238,972	$ 19	$ 140,495	$ (113,697)	$ 26,817
Stock-based compensation					829		829
Issuance of common stock on conversion of series B convertible preferred shares	(4,571)	(—)	914,200	1	(1)		—
Issuance of restricted stock units under equity incentive plans			245,588	—	434		434
Issuance of common stock held back on acquisition of Essentialis			1,084,034	1	(1)		—
Sale of shares to investors in the 2018 PIPE, net of costs of $250			10,272,375	11	16,239		16,250
Fair value at transaction date of warrants to purchase common stock under the 2018 PIPE					(582)		(582)
Net loss						(13,335)	(13,335)
Balances at December 31, 2018	—	—	31,755,169	32	157,413	(127,032)	30,413
Stock-based compensation					693		693
Issuance of restricted stock units under equity incentive plans			61,218	—	132		132
Sale of common stock in public offering, net of costs of $927			12,841,667	13	14,470		14,483
Net loss						(30,774)	(30,774)
Balances at December 31, 2019	—	$ —	44,658,054	$ 45	$ 172,708	$ (157,806)	$ 14,947

See accompanying notes to consolidated financial statements

Soleno Therapeutics, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	For the Years Ended December 31,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (30,774)	$ (13,335)
Loss from discontinued operations	—	(1,494)
Loss from continuing operations	(30,774)	(11,841)
Adjustments to reconcile net loss from continuing operations to net cash used in operating activities:		
Depreciation and amortization	1,958	1,963
Noncash lease expense	386	—
Stock-based compensation expense	825	1,263
Change in fair value of stock warrants	6,964	(522)
Change in fair value of contingent consideration	289	567
Gain on deconsolidation of former subsidiary	—	(1,994)
Operating loss of minority interest investment	478	160
Change in operating assets and liabilities:		
Prepaid expenses, other current assets and other assets	10	(60)
Due from related party	64	(64)
Accounts payable	1,061	249
Accrued compensation	9	(103)
Accrued clinical trial site costs	1,679	321
Operating lease liabilities	(360)	—
Other liabilities	36	(261)
Net cash used in continuing operating activities	(17,375)	(10,322)
Net cash used in discontinued operating activities	—	(1,361)
Net cash used in operating activities	(17,375)	(11,683)
Cash flows from investing activities:		
Purchases of property and equipment	(21)	(8)
Security deposit on sublease	(59)	—
Security deposit received from expired lease	108	—
Proceeds from sale of minority interest investment in former subsidiary	500	—
Net cash provided by (used in) continuing investing activities	528	(8)
Net cash used in discontinued investing activities	—	(172)
Net cash provided by (used in) investing activities	528	(180)
Cash flows from financing activities:		
Proceeds from sale of common stock and common stock warrants, net of costs	14,483	16,302
Principal paid on finance lease liabilities	(2)	—
Net cash provided by continuing financing activities	14,481	16,302
Net cash provided by discontinued financing activities	—	1,525
Net cash provided by financing activities	14,481	17,827
Net increase (decrease) in cash and cash equivalents from continuing operations	(2,366)	5,972
Net decrease in cash and cash equivalents from discontinued operations	—	(8)
Net increase (decrease) in cash and cash equivalents	(2,366)	5,964
Cash and cash equivalents, beginning of period	23,099	17,135
Cash and cash equivalents, end of period	$ 20,733	$ 23,099
Supplemental disclosures of non-cash investing and financing information		
Accrued liability for cost of issuing common stock	$ —	$ 52
Warrants issued in connection with sale of common stock	$ —	$ 582

See accompanying notes to consolidated financial statements.

Notes to Consolidated Financial Statements

Note 1. Overview

Soleno Therapeutics, Inc. (the “Company” or “Soleno”) was incorporated in the State of Delaware on August 25, 1999, and is located in Redwood City, California. On May 8, 2017, Soleno received stockholder approval to amend its Amended and Restated Certificate of Incorporation to change its name from “Capnia, Inc.” to “Soleno Therapeutics, Inc.” The Company is focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. Its lead candidate, Diazoxide Choline Controlled Release tablets, or DCCR, a once-daily oral tablet for the treatment of Prader-Willi Syndrome, or PWS, is currently being evaluated in a Phase III clinical development program.

The Company initially established its operations as a diversified healthcare company that developed and commercialized innovative diagnostics, devices and therapeutics addressing unmet medical needs, which consisted of: precision metering of gas flow technology marketed as Serenz® Allergy Relief, or Serenz, and the CoSense® End-Tidal Carbon Monoxide Monitor, or CoSense, which measures End-Tidal Carbon Monoxide and aids in the detection of excessive hemolysis, a condition in which red blood cells degrade rapidly and which can lead to adverse neurological outcomes; and, products that included temperature probes, scales, surgical tables, and patient surfaces.

On March 7, 2017, the Company completed its merger, or the Merger, with Essentialis, Inc., a Delaware corporation, or Essentialis, in accordance with the Merger Agreement by and between Soleno Therapeutics and Essentialis dated December 22, 2016, or the Merger Agreement. After the Merger, the Company’s primary focus has been the development and commercialization of novel therapeutics for the treatment of rare diseases. Essentialis was a privately-held, clinical-stage biotechnology company focused on the development of breakthrough medicines for the treatment of rare diseases in which there is increased mortality and risk of cardiovascular and endocrine complications. Prior to the Merger, Essentialis’s efforts were focused primarily on developing and testing product candidates that target the ATP-sensitive potassium channel, a metabolically-regulated membrane protein whose modulation has the potential to impact a wide range of rare metabolic, cardiovascular, and central nervous system diseases. Essentialis had tested DCCR as a treatment for PWS, a complex metabolic/neurobehavioral disorder. DCCR has orphan designation for the treatment of PWS in the United States, or U.S., as well as in the European Union, or E.U.

Subsequent to the Merger with Essentialis described above, the Company determined to divest, sell or dispose of its business efforts focused on the development and commercialization of its Serenz and CoSense technologies. Accordingly, and pursuant to ASC 205-20-45-10, any assets and liabilities related to the discontinued activities of CoSense and Serenz were presented separately as held for sale items, and the related operations reported herein for the CoSense and Serenz activities are reported as discontinued operations in the statements of operations.

The Company’s current research and development efforts are primarily focused on advancing its lead candidate, DCCR tablets, for the treatment of PWS, through late-stage clinical development.

Note 2. Going Concern and Management’s Plans

The Company had a net loss of $30.8 million during 2019 and has an accumulated deficit of $157.8 million at December 31, 2019 resulting from having incurred losses since its inception. The Company had $20.7 million of cash on hand at December 31, 2019 and used $17.4 million of cash in its operating activities during 2019. The Company has financed its operations principally through issuances of equity securities.

On October 25, 2019, the Company sold 12,841,667 shares of common stock in an underwritten public offering at a price of $1.20 per share for net proceeds of $14.5 million.

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

The Company expects to continue incurring losses for the foreseeable future and will be required to raise additional capital to complete its clinical trials, pursue product development initiatives and penetrate markets for the sale of its products. Management believes that the Company will continue to have access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations or other means, but the Company's access to such capital resources is uncertain and is not assured. If the Company is unable to secure additional capital, it may be required to curtail its clinical trials and development of new products and take additional measures to reduce expenses in order to conserve its cash in amounts sufficient to sustain operations and meet its obligations. These measures could cause significant delays in the Company's efforts to complete its clinical trials and commercialize its products, which is critical to the realization of its business plan and the future operations of the Company. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should it be unable to continue as a going concern.

Management believes that the Company does not have sufficient capital resources to sustain operations through at least the next twelve months from the date of this filing. Additionally, in view of the Company's expectation to incur significant losses for the foreseeable future it will be required to raise additional capital resources in order to fund its operations, although the availability of, and the Company's access to such resources is not assured. Accordingly, management believes that there is substantial doubt regarding the Company's ability to continue operating as a going concern within one year from the date of filing these financial statements.

Note 3. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, and the applicable rules and regulations of the Securities and Exchange Commission, or SEC.

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

Certain amounts from prior periods have been reclassified to conform to the current period presentation, including certain current liabilities within the Consolidated Balance Sheets and Consolidated Statements of Cash Flows, certain immaterial amounts within the Consolidated Statements of Operations, and the presentation of restricted stock units and the related expense within the Consolidated Statements of Stockholders' Equity and Consolidated Statements of Cash Flows.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities, and reported amounts of expenses in the financial statements and accompanying notes. Actual results could differ from those estimates. Key estimates included in the financial statements include the valuation of deferred income tax assets, the valuation of financial instruments, stock-based compensation, value and life of acquired intangibles, and the valuation of contingent liabilities for the purchase price of assets obtained through acquisition.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents at one U.S. commercial bank. Cash and cash equivalents deposited with this commercial bank exceeded the Federal Deposit Insurance Corporation insurable limit at December 31, 2019 and 2018. The Company expects the maintenance of balances in excess of insurable limits will continue.

Segments

The Company operates in one segment. Management uses one measurement of profitability and does not segregate its business for internal reporting, making operating decisions, and assessing financial performance. All long-lived assets are maintained in the United States of America.

Cash and Cash Equivalents

The Company considers all highly liquid investments, including its money market fund, purchased with an original maturity of three months or less to be cash equivalents. The Company's cash and cash equivalents are held in institutions in the U.S. and the U.K. and include deposits in a money market fund which was unrestricted as to withdrawal or use.

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of payments primarily related to insurance and short-term deposits. Prepaid expenses are initially recorded upon payment and are expensed as goods or services are received.

Patent

In March 2017, the Company completed the acquisition of Essentialis, Inc., a Delaware corporation, or Essentialis in accordance with the Merger Agreement by and between Soleno Therapeutics and Essentialis dated December 22, 2016. The merger transaction has been accounted for as an asset acquisition under the acquisition method of accounting and accordingly, the value of asset acquired in the amount of $22.0 million was assigned to the identifiable intangible asset relating to the patent for DCCR, which patent expires in June 2028.

Property and Equipment, Net

Property and equipment are stated at cost net of accumulated depreciation and amortization calculated using the straight-line method over the estimated useful lives of the assets, generally between three and five years. Leasehold improvements are amortized on a straight-line basis over the lesser of their useful life or the remaining term of the lease. Maintenance and repairs are charged to expense as incurred, and improvements are capitalized. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in operations in the period realized.

Equity Method Investment

Equity method investments are equity securities in investees not controlled by the Company, but over which the Company has the ability to exercise significant influence. The Company's equity method investment is measured at fair value minus impairment, if any, plus or minus the Company's share of equity method investee income or loss.

The Company's equity method investment in Capnia, Inc. is classified as Minority interest investment in former subsidiary in the consolidated balance sheet as of December 31, 2018 and was initially measured at fair value. (See Note 9.) The Company sold its equity method investment in Capnia in September 2019.

Long-Lived Assets

The Company reviews its long-lived assets for impairment annually and whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. The Company evaluates assets for potential impairment by comparing estimated future undiscounted net cash flows to the carrying amount of the asset. If the carrying amount of the assets exceeds the estimated future undiscounted cash flows, impairment is measured based on the difference between the carrying amount and the fair value of the assets.

Intangible Assets

Intangible assets with finite lives are amortized on a straight-line basis over their estimated useful lives of 11 years. The useful life of the intangible asset is evaluated each reporting period to determine whether events and circumstances warrant a revision to the remaining useful life.

Research and Development

Research and development costs are charged to operations as incurred. Research and development costs consist primarily of salaries and benefits, consultant fees, prototype expenses, certain facility costs and other costs associated with clinical trials, net of reimbursed amounts.

Costs to acquire technologies to be used in research and development that have not reached technological feasibility and have no alternative future use are expensed to research and development costs when incurred.

Certain research and development expenses are reported as discontinued operations. (See Note 9.)

Change in fair value of contingent consideration

The Company recorded the value of contingent future consideration to be paid for the acquisition of Essentialis as a liability in March 2017 at the date of the acquisition. The changes in value of the liability for the contingent consideration since the acquisition date are recorded as operating expense in the consolidated statements of operations.

Income Taxes

The Company accounts for income taxes using the asset and liability method. Under this method, deferred income tax assets and liabilities are recorded based on the estimated future tax effects of differences between the amounts at which assets and liabilities are recorded for financial reporting purposes and the amounts recorded for income tax purposes. A valuation allowance is provided against the Company’s deferred income tax assets when their realization is not reasonably assured.

The Company assesses all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position’s sustainability and is measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and the Company will determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available.

The loss from discontinued operations is reported net of the related effect for income taxes in the statements of operations.

Convertible Preferred Stock and other Hybrid Instruments

The Company’s convertible preferred stock was classified as permanent equity on its consolidated balance sheet in accordance with authoritative guidance for the classification and measurement of hybrid securities and distinguishing liability from equity instruments. The preferred stock is not redeemable at the option of the holder.

Further, the Company evaluated its Series B Convertible Preferred Stock and determined that it is considered an equity host under ASC 815, *Derivatives and Hedging*. In making this determination, the Company’s analysis followed the whole instrument approach which compares an individual feature against the entire preferred stock instrument which includes that feature. The Company’s analysis was based on a consideration of the economic characteristics and risks of its Series B Convertible Preferred Stock. More specifically, the Company evaluated all of the stated and implied substantive terms and features, including (i) whether the preferred stock included redemption features, (ii) how and when any redemption features could be exercised, (iii) whether the holders of preferred stock were entitled to dividends, (iv) the voting rights of the preferred stock and (v) the existence and nature of any conversion rights. As a result of the Company's conclusion that the preferred stock represents an equity host, the conversion feature of its Series B Convertible Preferred Stock is considered to be clearly and closely related to the associated preferred stock host instrument. Accordingly, the conversion feature in the preferred stock is not considered an embedded derivative that requires bifurcation.

Common Stock Purchase Warrants and Other Derivative Financial Instruments

The Company classifies common stock purchase warrants and other free standing derivative financial instruments as equity if the contracts (i) require physical settlement or net-share settlement or (ii) give the Company a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). The Company classifies any contracts that (i) require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside the control of the Company), (ii) give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement), or (iii) contain reset provisions as either an asset or a liability. The Company assesses classification of its freestanding derivatives at each reporting date to determine whether a change in classification between equity and liabilities is required. The Company determined that certain freestanding derivatives, which principally consist of Series A, Series C, the 2017 PIPE Warrants and 2018 PIPE Warrants, do not satisfy the criteria for classification as equity instruments due to the existence of certain cash settlement features that are not within the sole control of the Company or variable settlement provision that cause them to not be indexed to the Company's own stock.

Stock-Based Compensation

Stock-based compensation costs related to stock options and restricted stock units granted to employees, nonemployees and directors are measured at the date of grant based on the estimated fair value of the award. For restricted stock units this fair value is based on the Company's common stock price on the grant date. The Company estimates the grant date fair value of stock options, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. The grant date fair value of stock-based awards is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the award. Stock options generally vest over four years.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions to estimate the fair value of stock-based awards. If we had made different assumptions, our stock-based compensation expense, net loss and net loss per share of common stock could have been significantly different. These assumptions include:

- *Expected volatility:* The Company calculates the estimated volatility rate based the volatility of its common stock together with comparable companies in its industry.
- *Expected term:* The Company does not believe it is able to rely on its historical exercise and post-vesting termination activity to provide accurate data for estimating the expected term for use in estimating the fair value-based measurement of our options. Therefore, the Company has opted to use the "simplified method" for estimating the expected term of options.
- *Risk-free rate:* The risk-free interest rate is based on the yields of U.S. Treasury securities with maturities similar to the expected time to liquidity.
- *Expected divided yield:* The Company has never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. Consequently, it used an expected dividend yield of zero.

The Company accounts for forfeitures as they occur.

Recent Accounting Standards

Recently Adopted Accounting Standards

In February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Codification (ASC) 842, *Leases.* ASC 842 replaces the existing guidance in ASC 840, *Leases*, and requires lessees to capitalize most lease obligations as right-of-use assets with a corresponding liability on the balance sheet. Leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The guidance is effective for all public business entities and certain not-for-profit entities in fiscal years beginning after December 15, 2018, and for all other entities in fiscal years beginning after December 15, 2020. Early adoption is permitted. As the Company was an emerging growth company until December 31, 2019 and elected 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, it adopted the standard as of January 1, 2019 on December 31, 2019. The Company adopted ASC 842 using the optional modified retrospective method and will not restate comparative periods. The Company has elected to apply the "practical expedient package", which permits it to not reassess previous conclusions around lease identification, lease classification, and initial direct costs. Further, the Company will make an accounting policy election to exclude leases with terms of twelve months or less from the recognition requirements. The Company did not elect the use of the hindsight practical expedient. As a result of the adoption of the standard on January 1, 2019, the Company recognized lease liabilities based on the present value of the total fixed payments for its leases in the amount of approximately $322,000 and ROU assets of approximately $301,000 on its balance sheet. The adoption of the new standard did not have a material impact on the Company's Statement of Operations or Cash Flows.

In June 2018, the FASB issued ASU 2018-07, "*Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*", to simplify the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. Under the guidance, the measurement of equity-classified nonemployee awards is fixed at the grant date, which may lower the cost and reduce volatility in the income statement. This ASU was early adopted by the Company at the beginning of 2019. Its adoption did not have a material impact on the Company's consolidated financial statements.

In August 2018, SEC adopted the final rule under SEC Release No. 33-10532, *"Disclosure Update and Simplification*", amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must now be provided in a note or separate statement. The Company has applied this new guidance beginning in the first quarter of 2019.

Recently Issued Accounting Standards

In August 2018, the FASB issued ASU 2018-13, "*Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*". The ASU modifies the disclosure requirements for fair value measurements by removing, modifying, or adding certain disclosures. This ASU is effective for the Company beginning in 2020. Early adoption is permitted. An entity is permitted to early adopt any removed or modified disclosures upon issuance of ASU No. 2018-13 and delay adoption of the additional disclosures until their effective date. The adoption of this ASU is not expected to have a material impact on the Company's consolidated financial statements disclosures.

In December 2019, the FASB issued ASU 2019-12: *"Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes"*. The amendments in ASU 2019-12 simplify the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The amendments also improve consistent application of and simplify GAAP for other areas of Topic 740 by clarifying and amending existing guidance. The amendments in this Update are effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The Company has not yet assessed the potential impact of adopting ASU 2019-12 on its consolidated financial statements.

Note 4. Fair Value of Financial Instruments

The carrying value of the Company's cash, cash equivalents and accounts payable, approximate fair value due to the short-term nature of these items.

Fair value is defined as the exchange price that would be received for an asset or an exit price paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

- Level I — Unadjusted quoted prices in active markets for identical assets or liabilities;
- Level II — Inputs other than quoted prices included within Level I that are observable, unadjusted quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and
- Level III — Unobservable inputs that are supported by little or no market activity for the related assets or liabilities.

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands).

	Fair Value Measurements at December 31, 2019			
	Total	Level 1	Level 2	Level 3
Liabilities				
2017 PIPE warrant liability	$ 10,822	$ —	$ —	$ 10,822
2018 PIPE warrant liability	1,354	—	—	1,354
Essentialis purchase price contingency liability	5,938	—	—	5,938
Total common stock warrant and contingent consideration liability	$ 18,114	$ -	$ —	$ 18,114

	Fair Value Measurements at December 31, 2018			
	Total	Level 1	Level 2	Level 3
Liabilities				
Series A warrant liability	$ 49	$ 49	$ —	$ —
2017 PIPE warrant liability	4,563	—	—	4,563
2018 PIPE warrant liability	600	—	—	600
Essentialis purchase price contingency liability	5,649	—	—	5,649
Total common stock warrant and contingent consideration liability	$ 10,861	$ 49	$ -	$ 10,812

The Series A Warrant is a registered security that trades on the open market and the fair value of the Series A Warrant liability is based on the publicly quoted trading price of the warrants which is listed on and obtained from NASDAQ. Accordingly, the fair value of Series A Warrants is a Level 1 measurement. The fair value measurement of the Series C Warrants is based on significant inputs that are unobservable and thus represent Level 3 measurements. The Company's estimated fair value of the Series C Warrant liability is calculated using the Black-Scholes valuation model, which is equivalent to fair value computed using the Binomial Lattice Option Model. Key assumptions include the volatility of the Company's stock, the expected warrant term, expected dividend yield and risk-free interest rates. The Company's estimated fair value of the 2017 PIPE Warrants and the 2018 PIPE Warrants was calculated using a Monte Carlo simulation of a geometric Brownian motion model. The Monte Carlo simulation pricing model requires the input of highly subjective assumptions including the expected stock price volatility, the expected term, the expected dividend yield and the risk-free interest rate. The fair value of the Essentialis purchase price contingent liability is estimated using scenario-based methods based upon the Company's analysis of the likelihood of obtaining specified approvals from the Federal Drug Administration as well as reaching cumulative revenue milestones. The Level 3 estimates are based, in part, on subjective assumptions.

During the periods presented, the Company has not changed the manner in which it values liabilities that are measured at fair value using Level 3 inputs. The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy during the periods presented.

The following table sets forth a summary of the changes in the fair value of the Company's Level 1 and Level 3 warrants, which are treated as liabilities (dollars in thousands).

	Series A Warrants		Series C Warrants		2017 PIPE Warrants		2018 PIPE Warrants		Purchase Price Contingent Liability
	Number of Warrants	Liability	Number of Warrants	Liability	Number of Warrants	Liability	Number of Warrants	Liability	
Balance at January 1, 2019	485,121	$ 49	118,083	$ —	6,024,425	$ 4,563	513,617	$ 600	$ 5,649
Expiration of Series A Warrants	(485,121)	(49)	—	—	—	—	—	—	—
Change in value of Series C Warrants	—		—	—	—	—	—	—	—
Change in value of 2017 PIPE Warrants	—	—	—	—	—	6,259	—	—	—
Change in value of 2018 PIPE Warrants	—	—	—	—	—	—	—	754	—
Change in value of contingent liability	—	—	—	—	—	—	—	—	289
Balance at December 31, 2019	—	$ —	118,083	$ —	6,024,425	$ 10,822	513,617	$ 1,354	$ 5,938

Note 5. Other Financial Statement Details

Property and Equipment, Net

Property and equipment are summarized in the following table (in thousands).

	December 31, 2019	December 31, 2018
Computer hardware	$ 52	$ 67
Computer software	—	2
Furniture and fixtures	1	23
Leasehold improvements	—	13
	53	105
Less accumulated depreciation and amortization	(31)	(93)
Total	$ 22	$ 12

Depreciation expense was approximately $11,000 and $19,000 for the years ended December 31, 2019 and December 31, 2018, respectively.

Intangible Assets, Net

Intangible assets consist of the following (in thousands).

	December 31, 2019			December 31, 2018		
	Amount	Accumulated Amortization	Net Amount	Amount	Accumulated Amortization	Net Amount
Patents and merger costs	$ 22,003	$ (5,478)	$ 16,525	$ 22,003	$ (3,534)	$ 18,469
Total	$ 22,003	$ (5,478)	$ 16,525	$ 22,003	$ (3,534)	$ 18,469

Future amortization expense for intangible assets over their remaining useful lives is as follows (in thousands).

Year ending December 31	Patents and trademarks
2020	$ 1,944
2021	1,944
2022	1,944
2023	1,944
2024	1,944
2025 and thereafter	6,805
Total	$ 16,525

Amortization expense was $1.9 million for the year ended December 31, 2019 and 2018.

Note 6. Warrant Liabilities

The Company has issued multiple warrant series, of which the Series A Warrants, Series C Warrants, the 2017 PIPE Warrants and the 2018 PIPE Warrants (the “Warrants”) are considered liabilities pursuant to the guidance established by *ASC 815 Derivatives and Hedging.*

Accounting Treatment

The Company accounts for the Warrants in accordance with the guidance in *ASC 815*. As indicated above, the Company may be obligated to settle Warrants in cash in the case of a Fundamental Transaction.

The Company classified the Warrants as long-term liabilities at their fair value and will re-measure the warrants at each balance sheet date until they are exercised or expire. Any change in the fair value is recognized as other income (expense) in the Company’s consolidated statements of operations.

Series A Warrants

The Company issued 489,921 Series A Warrants to purchase shares of its common stock at an exercise price of $32.50 per share in connection with the unit offering offered in the Company’s initial public offering, or the IPO, in November 2014. The Series A Warrants were exercisable prior to the expiration of the five-year term on November 12, 2019.

Upon the completion of the IPO, the Series A Warrants started trading on the NASDAQ under the symbol SLNOW. As the Series A Warrants are publicly traded, the Company used the closing price on the measurement date to determine the fair value of the Series A Warrants. The Series AWarrants contain a fundamental transactions provision that permitted their settlement in cash at fair value at the option of the holder upon the occurrence of a change in control. Such change in control events include tender offers or hostile takeovers, which are not within the sole control of the Company as the issuer of these warrants. Accordingly, the Warrants were considered to have a cash settlement feature that precludes their classification as equity instruments. Settlement at fair value upon the occurrence of a fundamental transaction would be computed using the Black Scholes Option Pricing Model, which approximates the binomial lattice model.

Since their issuance, a total of 4,800 Series A Warrants have been exercised. On November 12, 2019, the remaining Series A Warrants expired. The decrease in fair value of approximately $49,000 from December 31, 2018 was recorded as other income (expense) in the consolidated statements of operations.

Series C Warrants

On March 5, 2015, the Company entered into separate agreements with certain Series B Warrant holders, who agreed to exercise their Series B Warrants to purchase an aggregate of 117,902 shares of the Company's common stock at an exercise price of $32.50 per share, resulting in the de-recognition of $6.7 million of the previously issued Series B Warrant liability and gross proceeds to the Company of $3.8 million based on the exercise price of the Series B Warrants. In April 2015, the Company issued a tender offer to the remaining holders of Series B Warrants to induce the holders to cash exercise the outstanding Series B Warrants in exchange for new Series C Warrants with an exercise price of $31.25 per share that expire on March 5, 2020. The tender offer was extended to Series B Warrant holders under a registration statement filed with the SEC on Form S-4, which was declared effective on June 25, 2015 and expired on July 24, 2015. During July 2015, certain Series B Warrant holder(s) tendered their Series B Warrants under the tender offer, which resulted in the issuance of 181 shares of the Company's common stock, the issuance of 181 Series C Warrants and proceeds to the Company of approximately $6,000.

In connection with this exercise of the Series B Warrants, the Company issued to each investor who exercised Series B Warrants, new Series C Warrants for the number of shares of the Company's common stock underlying the Series B Warrants that were exercised. Each Series C Warrant is exercisable at $31.25 per share and will expire on March 5, 2020. The Series C Warrants contract further provides for the payment of liquidated damages at an amount per month equal to 1% of the aggregate volume weighted average price, or VWAP, of the shares into which each Warrant is convertible into in the event that the Company is unable to maintain the effectiveness of a registration statement as described herein. The Company evaluated the registration payment arrangement stipulated in the terms of these securities and determined that it is probable that the Company will maintain an effective registration statement and has therefore not allocated any portion of the proceeds related to the warrant financings to the registration payment arrangement. The Warrants also contain a fundamental transactions provision that permits their settlement in cash at fair value at the option of the holder upon the occurrence of a change in control. Such change in control events include tender offers or hostile takeovers, which are not within the sole control of the Company as the issuer of these warrants. Accordingly, the Warrants are considered to have a cash settlement feature that precludes their classification as equity instruments. Settlement at fair value upon the occurrence of a fundamental transaction would be computed using the Black Scholes Option Pricing Model, which approximates the binomial lattice model.

The Series C Warrants are exercisable into 118,083 shares of the Company's common stock. As of December 31, 2019, the fair value of the Series C Warrants was determined to be zero, consistent with the value as of December 31, 2018.

The Company has calculated the fair value of the Series C Warrants using a Black-Scholes pricing model. The Black-Scholes pricing model requires the input of highly subjective assumptions including the expected stock price volatility. The Company used the following inputs.

	December 31, 2019	December 31, 2018
Volatility	90%	90%
Contractual term (years)	0.17	1.17
Expected dividend yield	—%	—%
Risk-free rate	1.52%	2.60%

Warrants Issued as Part of the Units in the 2017 PIPE Offering

The 2017 PIPE Warrants were issued on December 15, 2017 in the 2017 PIPE Offering, pursuant to a Warrant Agreement with each of the investors in the 2017 PIPE Offering, and entitle the holders to purchase 6,024,425 shares of the Company's common stock at an exercise price equal to $2.00 per share, subject to adjustment as discussed below, at any time commencing upon issuance of the 2017 PIPE Warrants and terminating at the earlier of December 15, 2020 or 30 days following positive Phase III results for the DCCR tablet in PWS.

The exercise price and number of shares of common stock issuable upon exercise of the 2017 PIPE Warrants may be adjusted in certain circumstances, including in the event of a stock split, stock dividend, extraordinary dividend, or recapitalization, reorganization, merger or consolidation. However, the exercise price of the 2017 PIPE Warrants will not be reduced below $1.72.

In the event of a change of control of the Company, the holders of unexercised warrants may present their unexercised warrants to the Company, or its successor, to be purchased by the Company, or its successor, in an amount equal to the per share value determined by the Black Scholes methodology.

As of December 31, 2019, the fair value of the 2017 PIPE Warrants was estimated at $10.8 million. The increase in the fair value of the liability for the 2017 PIPE Warrants of $6.3 million during the year ended December 31, 2019 was recorded as other expense in the consolidated statements of operations.

The Company has calculated the fair value of the 2017 PIPE Warrants using a Monte Carlo simulation of a geometric Brownian motion model. The Monte Carlo simulation pricing model requires the input of highly subjective assumptions including the expected stock price volatility. The following summarizes certain key assumptions used in estimating the fair values.

	December 31, 2019	December 31, 2018
Volatility	99%	75%
Contractual term (years)	1.0	2.0
Expected dividend yield	—%	—%
Risk-free rate	1.60%	2.51%

Warrants Issued as Part of the Units in the 2018 PIPE Offering

The 2018 PIPE Warrants were issued on December 19, 2018 in the 2018 PIPE Offering, pursuant to a Warrant Agreement with each of the investors in the 2018 PIPE Offering, and entitle the holders to purchase 513,617 shares of the Company's common stock at an exercise price equal to $2.00 per share, subject to adjustment as discussed below, at any time commencing upon issuance of the 2018 PIPE Warrants and terminating on December 21, 2023.

The exercise price and number of shares of common stock issuable upon exercise of the 2018 PIPE Warrants may be adjusted in certain circumstances, including in the event of a stock split, stock dividend, extraordinary dividend, or recapitalization, reorganization, merger or consolidation. However, the exercise price of the 2018 PIPE Warrants will not be reduced below $2.00.

In the event of a change of control of the Company, the holders of unexercised warrants may present their unexercised warrants to the Company, or its successor, to be purchased by the Company, or its successor, in an amount equal to the per share value determined by the Black Scholes methodology.

As of December 31, 2019, the fair value of the 2018 PIPE Warrants was estimated at $1.4 million. The approximate $754,000 increase in the fair value of the liability for the 2018 PIPE Warrants during the year ended December 31, 2019 was recorded as other expense in the consolidated statements of operations.

The Company has calculated the fair value of the 2018 PIPE Warrants using a Monte Carlo simulation of a geometric Brownian motion model. The Monte Carlo simulation pricing model requires the input of highly subjective assumptions including the expected stock price volatility.

The following summarizes certain key assumptions used in estimating the fair values.

	December 31, 2019	December 31, 2018
Volatility	99%	75%
Contractual term (years)	4.0	5.0
Expected dividend yield	—%	—%
Risk-free rate	1.56%	2.51%

The Monte Carlo simulation of a geometric Brownian motion model requires the use of highly subjective assumptions to estimate the fair value of stock-based awards. These assumptions include the following estimates.

- *Volatility:* The Company calculates the estimated volatility rate based on the volatilities of common stock of comparable companies in its industry together with the volatility of its own stock.
- *Contractual term:* The expected life of the warrants, which is based on the contractual term of the warrants.
- *Expected dividend yield:* The Company has never declared or paid any cash dividends and does not currently plan to pay cash dividends in the foreseeable future. Consequently, the Company used an expected dividend yield of zero.
- *Risk-free rate:* The risk-free interest rate is based on the U.S. Treasury rate for similar periods as those of expected volatility.

Note 7. Leases

Leases

The Company adopted ASC 842: Leases, as of January 1, 2019, using the modified retrospective method as described in Note 3, without adjusting prior comparative periods.

The Company determines whether an arrangement is a lease at inception. Specifically, it considers whether it controls the underlying asset and has the right to obtain substantially all the economic benefits or outputs from the asset. If the contractual arrangement contains a lease, the Company then determines the classification of the lease, operating or finance, using the classification criteria described in ASC 842. The Company has elected not to separate lease components from non-lease components, such as common area maintenance charges, and instead accounts for the lease and non-lease components as a single component.

The Company's previous operating lease for its headquarters facility office space in Redwood City, California, terminated in August 2019, along with the related subleases. One of the subleases was with Capnia, of which the Company was a joint owner until September 2019. See note 9 for further information. Sublease income received from Capnia during the year ended December 31, 2019 was approximately $65,000.

In July 2019, the Company executed a non-cancellable lease agreement for 6,368 square feet of new space in Redwood City, California, which began in September 2019 and expires in May 2021. The lease also provides the Company with the right to use office furniture in the space and allows the purchase of this furniture at the end of the lease term for $1. The lease agreement requires monthly lease payments of approximately $29,000 beginning in November of 2019, with an increase to approximately $30,000 per month in September of 2020. The Company has accounted for the new lease as an operating lease for the office space and a finance lease for the office furniture, based on their relative standalone prices.

As of December 31, 2019, the Company's operating lease right-of-use assets and finance lease right-of-use assets were approximately $398,000 and $24,000, respectively. The Company's current operating lease liabilities were approximately $305,000 as of December 31, 2019. Each of these amounts appears as a separate line within the Company's consolidated balance sheet. The Company's current finance lease liabilities were approximately $17,000 as of December 31, 2019 and are included in other current liabilities on the consolidated balance sheet. As of December 31, 2019 the Company's long-term operating lease liabilities were approximately $139,000 and the long-term finance lease liabilities were approximately $8,000, both of which are included in other long-term liabilities on the consolidated balance sheet.

The components of lease expense during the year ended December 31, 2019 were as follows (in thousands):

Operating lease cost:		
Operating lease cost	$	418
Sublease income		(173)
Total operating lease cost	$	245
Finance lease cost:		
Amortization of right-of-use assets	$	3
Interest on lease liabilities		1
Total finance lease cost	$	4

For the year ended December 31, 2018, rent expense was approximately $323,000, net of sublease income of approximately $277,000.

Supplemental cash flow information related to leases was as follows for the year ended December 31, 2019 (in thousands):

Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$	219
Operating cash flows from finance leases	$	1
Financing cash flows from finance leases	$	2
Right-of use assets obtained in exchange for lease obligations (noncash):		
Operating leases	$	484
Finance leases	$	27

The following is a schedule by year of future maturities of the Company’s lease liabilities as of December 31, 2019 (in thousands):

	Operating Leases		Finances Lease	
2020	$	336	$	19
2021		143		8
Total lease payments		479		27
Less interest		(34)		(2)
Total	$	445	$	25

The weighted-average remaining lease term and discount rate related to the Company’s lease liabilities as of December 31, 2019 were 1.4 years and 10%, respectively, for both the operating leases and finance leases. The Company lease discount rates are based on estimates of its incremental borrowing rate, as the discount rates implicit in the Company’s leases cannot be readily determined. As the Company does not have any outstanding debt the Company estimates the incremental borrowing rate based on its estimated credit rating and available market information.

Note 8. Commitments and Contingencies

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company’s exposure under these agreements is unknown because it involves claims that may be made against the Company in the future but have not yet been made. The Company accrues a liability for such matters when it is probable that future expenditures will be made, and such expenditures can be reasonably estimated.

Note 9. CoSense Joint Venture Agreement and Discontinued Operations

In December 2017, the Company entered into a joint venture with OptAsia Healthcare Limited, or OAHL, with respect to its CoSense product by agreeing to sell shares of Capnia, its then wholly-owned subsidiary, to OAHL. CoSense was Soleno’s first Sensalyze Technology Platform product to receive 510(k) clearances from the FDA and CE Mark certification. The Company’s entry into the joint venture resulted from a comprehensive review of strategic alternatives for its legacy products and product candidates following its transition to a primarily therapeutic drug product company. The terms of the Joint Venture Agreement provide that OAHL would invest up to a total of $2.2 million in Capnia’s common shares on an incremental quarterly basis commencing in December 2017. OAHL was also responsible for funding a portion of the Capnia operations. The Joint Venture Agreement provided that Capnia would issue shares of common stock to OAHL based on a negotiated price of $1.00 per share when the cumulative investment made by OAHL equaled or exceeded $1.2 million. For financial reporting purposes, Capnia’s assets, liabilities and results of operations had historically been consolidated with those of the Company.

During October 2018, the Company and OAHL determined and agreed that the cumulative investment made by OAHL exceeded $1.2 million during the quarter ended September 30, 2018. Accordingly, on October 16, 2018, Capnia issued 1,690,322 shares of its common stock to OAHL, representing 53% of its outstanding shares. After the share issuance the Company no longer held a controlling interest in Capnia and resulted in the deconsolidation of Capnia’s financial statements from those of the Company and a $2.0 million gain was recognized in the fourth quarter of 2018 as a result of the deconsolidation. Of this amount, $1.2 million related to the remeasurement of the Company's retained interest in the joint venture to fair value which was measured based on the negotiated price of $1.00 per share for Soleno’s remaining ownership of 1,480,000 shares less a 23% discount for lack of control over Capnia. The total gain was included in other income from continuing operations on the Company's consolidated statements of operations. The remaining 47% investment in Capnia was classified as an equity method investment and presented as a Minority interest investment in former subsidiary in the consolidated balance sheet. During September 2019, the Company sold its remaining 47% investment in Capnia to Sinon for a total purchase price of $500,000. As of the sale date, the Company had a minority interest investment in former subsidiary balance of approximately $467,000, after recording approximately $511,000 for its share of Capnia’s losses during 2019 up until the date of sale, which is included in the line titled “Loss from minority interest investment” in the Company’s consolidated statements of operations. A gain of approximately $33,000 was recognized upon the sale and is presented, together with the Company’s share of Capnia’s net losses during the period, in the consolidated statements of operations in the line titled “Loss from minority interest investment”. Following the transaction, the Company has no interest remaining in Capnia and the previous joint venture agreement with OAHL has been terminated.

There were no assets or liabilities held for sale as of December 31, 2019, or December 31, 2018, after the deconsolidation of Capnia in October 2018, and no discontinued operations during the year ended December 31, 2019. The components of the Statements of Operations presented as Discontinued Operations during the year ended December 31, 2018 follow (in thousands).

Product revenue	$	62
Cost of product revenue		32
Gross profit		30
Expenses		
Research and development		1,106
Sales and marketing		25
General and administrative		393
Total expenses		1,524
Operating loss		(1,494)
Net loss from discontinued operations	$	(1,494)

Stock-based compensation expense of approximately $76,000 and was classified in discontinued operations for the years ended December 31, 2018. There were no discontinued operations during the year ended December 31, 2019.

Note 10. Stockholders’ Equity

Convertible Preferred Stock

The Company is authorized to issue 10,000,000 shares of Preferred Stock.

The Company had issued a total of 13,780 shares of Series B Convertible Preferred Stock pursuant to the Securities Purchase Agreement entered into on June 29, 2016 with Sabby Management, LLC. As of December 31, 2019, there were no shares of Series B Convertible Preferred Stock outstanding as all such previously issued shares had been converted to common shares.

Common Stock

On March 7, 2017, the Company completed the Merger with Essentialis and issued 3,783,388 shares of common stock to shareholders of Essentialis. Pursuant to the terms of the Merger Agreement, the Company held back shares of common stock as partial recourse to satisfy indemnification claims. Effective March 7, 2018, on the one-year anniversary of the closing of the merger, the Company issued 180,667 shares for the previously held back amount. In the second quarter of 2018 there were 903,367 additional shares of common stock issued upon the achievement of a development milestone. In total, 4,867,422 shares of common stock were issued to Essentialis stockholders. Additionally, upon the achievement of certain commercial milestones associated with the sale of Essentialis' product in accordance with the terms of the Merger Agreement, the Company is obligated to make cash earnout payments of up to a maximum of $30.0 million to Essentialis stockholders. The merger consideration described above will be reduced by any such shares of common stock issuable, or cash earnout payments payable, to Essentialis' management carve-out plan participants and other service providers of Essentialis, in each case, in accordance with the terms of the Merger Agreement.

On January 27, 2017, the Company entered into the 2017 Aspire Purchase Agreement with Aspire Capital, which provided that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital was committed to purchase up to an aggregate of $17.0 million in value of shares of the Company's common stock over the 30-month term of the purchase agreement. Additionally, on the date of the closing of the financing, as defined in the Merger Agreement, the Company issued to Aspire Capital, and Aspire Capital purchased from the Company an aggregate of $2.0 million of the Company's common stock.

On December 19, 2018, the Company entered into a Securities Purchase Agreement with certain purchasers, pursuant to which the Company sold and issued 10,272,375 units at a price per unit of $1.61, for aggregate gross proceeds of $16.5 million. Each unit consisted of one share of the Company's common stock and a warrant to purchase 0.05 shares of the Company's common stock at an exercise price of $2.00 per share, for an aggregate of 10,272,375 shares of common stock and corresponding warrants to purchase an aggregate of 513,617 shares of common stock, together with the shares of common stock are referred to as the 2018 Resale Shares. The Company also granted certain registration rights to these stockholders, pursuant to which, among other things, the Company prepared and filed a registration statement with the SEC to register for resale the 2018 Resale Shares. The registration statement was declared effective in April 2019.

On October 25, 2019, the Company sold 12,841,667 shares of its common stock, including 1,675,000 shares sold upon full exercise of the underwriters' option to purchase additional shares, at a public offering price of $1.20 per share. The net proceeds of the offering were $14.5 million, after deducting the underwriting discount and other offering expenses.

Equity Incentive Plans

The Company has the 2014 Equity Incentive Plan, or the 2014 Plan. Under the 2014 Plan the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units, performance units or performance shares to employees, directors, advisors, and consultants. Options granted under the 2014 Plan may be incentive stock options ("ISOs") or nonqualified stock options ("NSOs"). ISOs may be granted only to Company employees, including officers and directors.

The Board of Directors has the authority to determine to whom stock options will be granted, the number of options, the term, and the exercise price. Options are to be granted at an exercise price not less than fair value. For individuals holding more than 10% of the voting rights of all classes of stock, the exercise price of an option will not be less than 110% of fair value. The vesting period is normally monthly over a period of 4 years from the vesting date. The contractual term of an option is no longer than five years for ISOs for which the grantee owns greater than 10% of the voting power of all classes of stock and no longer than ten years for all other options. The terms and conditions governing restricted stock units is at the sole discretion of the Board. As of December 31, 2019, a total of 615,760 shares are available for future grant under the 2014 Plan.

The Company recognized stock-based compensation expense related to options and restricted stock units granted to employees, directors and consultants for the years ended December 31, 2019 and 2018 of approximately

$825,000 and $1.3 million, respectively, of which approximately $76,000 was recorded in discontinued operations in 2018. There were no discontinued operations during 2019. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the statements of operations for stock-based compensation arrangements during the year ended December 31, 2019 and December 31, 2018.

Stock compensation expense was allocated between departments in continuing operations as follows (in thousands).

	Year ended	
	December 31, 2019	December 31, 2018
Research and development	$ 158	$ 205
General and administrative	667	982
Total	$ 825	$ 1,187

Stock Options

The Company granted options to purchase 658,285 and 756,086 of the Company's common stock in 2019 and 2018, respectively. The fair value of each award granted was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions.

	Year Ended	
	December 31, 2019	December 31, 2018
Expected life (years)	5.5-6.1	5.5-6.0
Risk-free interest rate	1.6%-2.6%	2.7%-2.8%
Volatility	70%-75%	70%-71%
Dividend rate	— %	— %

The Black-Scholes option-pricing model requires the use of highly subjective assumptions to estimate the fair value of stock-based awards. These assumptions include the following estimates:

- *Expected life:* The expected life of stock options represents the average of the contractual term of the options and the weighted-average vesting period, as permitted under the simplified method. The Company does not believe it is able to rely on historical exercise and post-vesting termination activity to provide accurate data for estimating the expected term for use in estimating the fair value-based measurement of stock options. Therefore, it has opted to use the "simplified method" for estimating the expected term of options.
- *Risk-free interest rate:* The risk-free interest rate is based on the yields of U.S. Treasury securities with maturities similar to the expected time to liquidity.
- *Volatility:* The estimated volatility rate based on the volatilities of the Company's common stock together with comparable companies in the Company's industry.
- *Dividend rate:* The Company has never declared or paid any cash dividends and does not presently plan to pay cash dividends in the foreseeable future. Consequently, the Company used an expected dividend yield of zero.

The following table summarizes stock option and restricted stock unit transactions for the years ended December 31, 2019 and 2018 as issued under the 2014 Plan.

	Shares Available for Grant	Number of Options Outstanding	Weighted-Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in years)
Balance at January 1, 2018	1,571,212	1,026,987	$ 9.99	7.94
Additional shares authorized	223,742			
Shares allocated to grants of restricted stock units	(245,588)			
Options granted	(756,086)	756,086	$ 1.68	
Options exercised	—	—	—	—
Options canceled/forfeited	115,920	(115,920)	$ 12.72	—
Balance at December 31, 2018	909,200	1,667,153	$ 6.03	8.27
Additional shares authorized	223,742			
Shares allocated to grants of restricted stock units	(61,218)			
Options granted	(658,285)	658,285	$ 1.77	
Options exercised	—	—	—	—
Options canceled/forfeited	202,321	(202,321)	$ 6.99	—
Balance at December 31, 2019	615,760	2,123,117	$ 4.62	7.87
Options vested at December 31, 2019		1,153,457	$ 6.91	7.24
Options vested and expected to vest at December 31, 2019		2,123,117	$ 4.62	7.87

The weighted-average grant date fair value of employee options granted was $1.14 and $1.08 per share for the year ended December 31, 2019 and December 31, 2018, respectively. At December 31, 2019 total unrecognized employee stock-based compensation was $1.1 million, which is expected to be recognized over the weighted-average remaining vesting period of 2.4 years. As of December 31, 2019, the outstanding stock options had an intrinsic value of $1.6 million.

Restricted Stock Units

There were 61,218 and 245,588 restricted stock units granted by the Company during the year ended December 31, 2019 and December 31, 2018, respectively, to employees, directors and consultants. The shares were 100% vested on the grant date and were valued based on the Company's common stock price on the grant date, with approximately $132,000 and $434,000 of related stock-based compensation expense recognized during the year ended December 31, 2019 and December 31, 2018, respectively.

2014 Employee Stock Purchase Plan

The Company's board of directors and stockholders have adopted the 2014 Employee Stock Purchase Plan, or the ESPP. The ESPP has become effective, and the board of directors will implement commencement of offers thereunder in its discretion. A total of 27,967 shares of the Company's common stock has been made available for sale under the ESPP. In addition, the ESPP provides for annual increases in the number of shares available for issuance under the plan on the first day of each year beginning in the year following the initial date that the board of directors authorizes commencement, equal to the least of:

- 1.0% of the outstanding shares of the Company's common stock on the first day of such year;
- 55,936 shares; or
- such amount as determined by the board of directors.

As of December 31, 2019, there were no purchases by employees under this plan.

Series D Warrants

The Company issued 256,064 Series D Warrants in October 2015, which are exercisable into 586,182 shares of the Company's common stock, with an exercise price of $12.30 and a term of five years expiring on October 15, 2020. The Company's Series D Warrants contain standard anti-dilution provisions for stock dividends, stock splits, subdivisions, combinations and similar types of recapitalization events. They also contain a cashless exercise feature that provides for their net share settlement at the option of the holder in the event that there is no effective registration statement covering the continuous offer and sale of the warrants and underlying shares. The Company is required to comply with certain requirements to cause or maintain the effectiveness of a registration statement for the offer and sale of these securities. The Series D Warrant agreement further provides for the payment of liquidated damages at an amount per month equal to 1% of the aggregate VWAP of the shares into which each Series D Warrant is convertible into in the event that the Company is unable to maintain the effectiveness of a registration statement as described herein. The Company evaluated the registration payment arrangement stipulated in the terms of this securities agreement and determined that it is probable that the Company will maintain an effective registration statement and has therefore not allocated any portion of the proceeds to the registration payment arrangement. The Series D Warrant agreement specifically provides that under no circumstances will the Company be required to settle any Series D Warrant exercise for cash, whether by net settlement or otherwise.

Accounting Treatment

The Company accounts for the Series D Warrants in accordance with the guidance in ASC 815 *Derivatives and Hedging.* As indicated above, the Company is not required under any circumstance to settle any Series D Warrant exercise for cash. The Company has therefore classified the value of the Series D Warrants as permanent equity.

Other Common Stock Warrants

As of December 31, 2019, the Company had 102,070 common stock warrants outstanding from the 2010/2012 convertible notes, with an exercise price of $24.35 and a term of 10 years expiring in November 2024. The Company also had outstanding 16,500 common stock warrants issued to the underwriter in the Company's IPO, with an exercise price of $35.70 and a term of 10 years, expiring in November 2024.

Note 11. Income Taxes

The geographical distribution of loss before income taxes are summarized below (in thousands).

	December 31, 2019	December 31, 2018
United States	$ (30,729)	$ (11,830)
Foreign	(45)	(11)
Loss before income taxes	$ (30,774)	$ (11,841)
Loss resulting from discontinued operations	$ —	$ (1,494)
Taxes allocated to discontinued operations	$ —	$ —

The provision for income tax benefit differs from the amount estimated by applying the statutory federal income tax rate to the operating loss from continuing operations due to the following (in thousands).

	December 31, 2019	December 31, 2018
Tax on the loss before income tax expense computed at the federal statutory rate	$ (6,463)	$ (2,486)
State tax (benefit) at statutory rate, net of federal benefit	(1,691)	(187)
Foreign rate differential	10	2
Change in valuation allowance	6,696	4,143
Change in research and development credits	(200)	(99)
Stock based compensation—ISOs	149	143
Change in fair value of warrants	1,461	(110)
Change in fair value of contingent consideration	61	119
Gain on deconsolidation	—	(4)
Disallowance of loss on discontinued operations	—	(426)
Change in net operating loss true up	(725)	(590)
Change in state rate true up	701	—
Change in temporary difference true up	—	(456)
Other	1	(49)
Provision for income tax benefit	$ —	$ —

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities are as follows at December 31, 2019 and 2018 (in thousands).

	December 31, 2019	December 31, 2018
Non-current deferred tax assets:		
Federal and state net operating loss carryforwards	$ 35,091	$ 28,532
Research and other credits	2,349	2,037
Reserves and accruals	77	52
Assets held for sale	—	15
Fixed assets	71	67
Capital loss carryover	1,115	425
Stock based compensation	85	70
Lease liability	131	—
Other deferred tax assets	196	542
Gross non-current deferred tax assets	39,115	31,740
Intangible assets	(4,623)	(4,062)
Right-of-use assets	(118)	—
Total non-current deferred tax liabilities	(4,741)	(4,062)
Total deferred tax assets	34,374	27,678
Valuation allowance	(34,374)	(27,678)
Net deferred tax assets	$ —	$ —

The Company has recorded a full valuation allowance against its net deferred tax assets due to the uncertainty as to whether such assets will be realized. The valuation allowance increased by $6.7 million from December 31, 2018 to December 31, 2019 primarily due to the generation of current year net operating losses, capital losses and research and development credits claimed.

As of December 31, 2019, the Company had $150.5 million of federal, $82.5 million of state and approximately $299,000 of foreign net operating losses available to offset future taxable income. The federal net operating loss carryforwards begin to expire in 2020, the federal net operating loss carryforwards of $31.7 million may be carried forward indefinitely, the state net operating loss carryforwards will begin to expire in 2028 and the foreign net operating loss carryforward can be carried forward indefinitely, if not utilized. The Company adjusted its state net operating loss carryforward by $10.4 million for the year ended December 31, 2018. As of December 31, 2019, the Company also had $1.4 million of federal and approximately $916,000 of state research and development credit carryforwards. The federal research and development credit carryforward begin to expire in 2024 and the state research and development credit can be carried forward indefinitely.

Utilization of the net operating loss and tax credit carry forwards are subject to an annual limitation due to the ownership percentage change limitations provided by the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of the net operating loss before utilization. The Company completed Section 382 analysis through December 2016 and determined that an ownership change, as defined under Section 382 of the Internal Revenue Code, occurred in June 2016. The Company's tax attributes are subject to an annual limitation of $0.5 million per year for federal purposes. For years ended after December 31, 2016, the utilization of net operating losses and tax credit carryforwards are subject to further limitation in the event an additional ownership change were to occur for tax purposes. The Company has not completed an updated analysis of whether there was an ownership change, as defined under Section 382 of the Internal Revenue Code, resulting from the issuance of new shares during 2018 through 2019 and, as such, is not able at this time to determine the impact on the net operating loss ("NOL") carryforwards, if any, as of the date of these consolidated financial statements.

United States taxes and foreign withholding taxes have not been provided on undistributed earnings for certain non-United States subsidiaries as of December 31, 2019, as the earnings, if any, are intended to be indefinitely reinvested.

The following tables summarize the activities of gross unrecognized tax benefits (in thousands).

	December 31,	
	2019	2018
Beginning balance	$ 964	$ 854
Increase related to prior year tax positions	7	23
Decrease related to prior year tax positions	(4)	—
Increase related to current year tax positions	144	87
Ending balance	$ 1,111	$ 964

The Company uses the “more likely than not” criterion for recognizing the tax benefit of uncertain tax positions and to establish measurement criteria for income tax benefits. The Company has determined it has $1.1 million of unrecognized assets and liabilities related to uncertain tax positions as of December 31, 2019. Changes in the unrecognized tax benefits within the next 12 months are expected to be similar to prior years and should not significantly increase or decrease. In the event the Company should need to recognize interest and penalties related to unrecognized tax liabilities, this amount will be recorded as a component of other expense.

There were no unrecognized tax benefits that would impact the effective tax rate as of December 31, 2019 and December 31, 2018. As of December 31, 2019, unrecognized tax benefits of $1.1 million would be offset by a change in valuation allowance.

The Company files income tax returns in the U.S. federal jurisdiction, certain state jurisdictions and United Kingdom. In the normal course of business, the Company is subject to examination by federal, state, local and foreign jurisdictions, where applicable. In the U.S federal jurisdiction, tax years 1999 forward remain open to examination, in the state tax jurisdiction, years 2008 forward remain open to examination and in the foreign jurisdiction, years 2015 forward remain open to examination. The Company is currently not under audit by any federal, state, local or foreign jurisdiction.

The Jobs Act also establishes global intangible low-taxed income, or “GILTI,” provisions that impose a tax on foreign income in excess of a deemed return on intangible assets of foreign corporations. The Company’s accounting policy for the income tax effects of GILTI will be to recognize those taxes as expenses in the period incurred. In 2019, the Company’s foreign subsidiary realized a tested loss for the period and therefore, the Company did not have a GILTI inclusion for the year.

Note 12. Net loss per share

Basic net loss per share is computed by dividing net loss by the weighted-average number of common stock actually outstanding during the period. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common stock outstanding and dilutive potential common stock that would be issued upon the exercise of common stock warrants and options. For the years ended December 31, 2019 and 2018, the effect of issuing the potential common stock is anti-dilutive due to the net losses in those periods and the number of shares used to compute basic and diluted earnings per share are the same in each of those periods.

The following potentially dilutive securities outstanding have been excluded from the computations of diluted weighted-average shares outstanding because such securities have an antidilutive impact due to losses reported (in common stock equivalent shares).

	As of December 31,	
	2019	2018
Warrants issued to 2010/2012 convertible note holders to purchase common stock	102,070	102,070
Options to purchase common stock	2,123,117	1,667,153
Warrants issued in 2009 to purchase common stock	—	1,851
Warrants issued to underwriter to purchase common stock	16,500	16,500
Series A warrants to purchase common stock	—	485,121
Series C warrants to purchase common stock	118,083	118,083
Series D warrants to purchase common stock	586,162	586,162
2017 PIPE warrants	6,024,425	6,024,425
2018 PIPE warrants	513,617	513,617
Total	9,483,974	9,514,982

Note 13. Defined Contribution Plan

The Company sponsors a 401(k) Plan, which stipulates that eligible employees can elect to contribute to the 401(k) Plan, subject to certain limitations of eligible compensation. The Company may match employee contributions in amounts to be determined at the Company's sole discretion. During the year ended December 31, 2019 the Company made matching contributions of approximately $37,000 to the 401(k) Plan. No contributions were made during the year ended December 31, 2018.

Note 14. Subsequent Events

The Company has evaluated its subsequent events from December 31, 2019 through the date these consolidated financial statements were issued and has determined that there are no subsequent events requiring disclosure in these consolidated financial statements.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in U.S. Securities and Exchange Commission, or SEC, rules and forms, and that such information is accumulated and communicated to our management to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Our Principal Executive Officer and Principal Financial Officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Annual Report on Form 10-K, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, with the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our Principal Executive Officer and Principal Financial Officer as appropriate to allow timely decisions regarding required disclosure.

Internal Control over Financial Reporting

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. Internal control over financial reporting is a process designed by, or under the supervision of, our Principal Executive Officer and Principal Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP, including those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and the disposition of our assets, (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with GAAP and that receipts and expenditures are being made only in accordance with authorizations of our management and board of directors, and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the consolidated financial statements.

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

Management conducted an evaluation of the effectiveness of our control over financial reporting based on the 2013 framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2019.

Changes in Internal Controls

There have been no changes to our internal control over financial reporting that occurred during our last fiscal quarter ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our 2020 Annual Meeting of Stockholders. The Definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our 2020 Annual Meeting of Stockholders. The Definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our 2020 Annual Meeting of Stockholders. The Definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our 2020 Annual Meeting of Stockholders. The Definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our 2020 Annual Meeting of Stockholders. The Definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

1. Financial Statements: See “Index to Financial Statements” in Part II, Item 8 of this Annual Report on Form 10-K

2. Financial Schedules: All schedules have been omitted because the information called for is not required or is shown either in the financial statements or in the notes thereto.

3. Exhibits: The exhibits listed in the accompanying index to exhibits are filed or incorporated by reference as part of this Annual Report on Form 10-K.

EXHIBIT INDEX

Exhibit Number	Description of Document	Incorporated by Reference from Registrant's Form	Date Filed with the SEC	Exhibit Number	Filed Herewith
2.1	Stock Purchase Agreement, dated as of July 18, 2017, and between Soleno Therapeutics, Inc., a Delaware corporation, and NeoForce Holdings, Inc. a Delaware corporation	8-K	July 24, 2017	2.1	
2.2	Joint Venture Agreement, dated as of December 4, 2017, by and among Soleno Therapeutics, Inc., Capnia, Inc., and OptAsia Healthcare Limited	8-K	December 8, 2017	2.1	
2.3	PRC IP Purchase Agreement, dated as of December 4, 2017, by and between OptAsia Healthcare Limited and Capnia, Inc.	8-K	December 8, 2017	2.2	
2.4	Transition Services Agreement, dated as of December 4, 2017, by and among Soleno Therapeutics, Inc., a Delaware corporation, Capnia, Inc. and OptAsia Healthcare, Ltd., a Hong Kong company	8-K	December 8, 2017	2.3	
3.1	Amended and Restated Certificate of Incorporation of Soleno Therapeutics, Inc.	S-1/A	August 7, 2014	3.2	
3.2	Amended and Restated Bylaws of Soleno Therapeutics, Inc.	S-1/A	July 1, 2014	3.4	
3.3	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock.	8-K	October 15, 2015	3.1	
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock	8-K	July 6, 2016	3.1	
3.5	Certificate of Amendment	8-K	May 11, 2017	3.1	
3.6	Certificate of Amendment to the Certificate of Incorporation	8-K	October 6, 2017	3.1	
4.1	Form of the common stock certificate.	S-1/A	August 5, 2014	4.1	
4.2	Amended And Restated Investors' Rights Agreement, dated March 20, 2008, by and among Soleno Therapeutics, Inc. and certain holders of the Soleno Therapeutics, Inc.'s capital stock named therein.	S-1/A	July 1, 2014	4.2	
4.3	Form of Series A Warrant Agreement.	S-1/A	August 5, 2014	4.3	
4.4	Form of the Series A Warrant certificate.	S-1/A	August 5, 2014	4.4	
4.5	Form of Underwriters' Compensation Warrant.	S-1/A	August 5, 2014	4.5	

Exhibit Number	Description of Document	Incorporated by Reference from Registrant's Form	Date Filed with the SEC	Exhibit Number	Filed Herewith
4.6	Form of Convertible Promissory Note issued in February 2010 and March 2010 in connection with the 2010 convertible note financing.	S-1	June 10, 2014	4.6	
4.7	Form of Warrant to Purchase Shares issued in February 2010 and March 2010 in connection with the 2010 convertible note financing.	S-1	June 10, 2014	4.7	
4.8	Form of Convertible Promissory Note issued in November 2010 in connection with the 2010 convertible note financing.	S-1	June 10, 2014	4.8	
4.9	Form of Warrant to Purchase Shares issued in November 2010 in connection with the 2010 convertible note financing.	S-1	June 10, 2014	4.9	
4.10	Form of Convertible Promissory Note issued in January 2012 in connection with the 2012 convertible note financing.	S-1	June 10, 2014	4.10	
4.11	Form of Warrant to Purchase Shares issued in January 2012 in connection with Soleno Therapeutics, Inc.'s 2012 convertible note financing.	S-1	June 10, 2014	4.11	
4.12	Form of Convertible Promissory Note issued in July 2012 and August 2012 in connection with the 2012 convertible note financing.	S-1	June 10, 2014	4.12	
4.13	Form of Warrant to Purchase Shares issued in July 2012 and August 2012 in connection with the 2012 convertible note financing.	S-1	June 10, 2014	4.13	
4.14	Form of Convertible Promissory Note issued in April, August and October 2014 in connection with the 2014 convertible note financing.	S-1	June 10, 2014	4.14	
4.15	Form of Warrant to Purchase Shares issued in April, August and October 2014 in connection with the 2014 convertible note financing.	S-1	June 10, 2014	4.15	
4.16	Form of unit certificate.	S-1/A	August 5, 2014	4.16	
4.17	Form of Series B Warrant Agreement.	S-1/A	November 4, 2014	4.17	
4.18	Form of the Series B Warrant certificate.	S-1/A	November 4, 2014	4.18	
4.19	Form of the Series C Warrant Agreement.	S-4	April 1, 2015	4.19	
4.20	Form of the Series C Warrant certificate.	S-4	April 1, 2015	4.20	
4.21	Form of Series D Common Stock Purchase Warrant.	8-K	October 15, 2015	4.1	

Exhibit Number	Description of Document	Incorporated by Reference from Registrant's Form	Date Filed with the SEC	Exhibit Number	Filed Herewith
4.22	Form of Placement Agent Warrant.	8-K	October 15, 2015	4.2	
4.23	Form of Series D common stock Warrant Certificate.	8-K	October 15, 2015	4.3	
4.24	Form of Series A Convertible Preferred Stock Certificate.	8-K	October 15, 2015	4.4	
4.25	Form of Placement Agent Warrant.	8-K	July 6, 2016	4.1	
4.26	Form of Series B Convertible Preferred Stock Certificate.	8-K	July 6, 2016	4.2	
4.27	Form of Common Stock Purchase Warrant	8-K	December 13, 2017	4.1	
4.28	Form of Common Stock Purchase Warrant	8-K	December 19, 2018	4.1	
4.29	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934				X
9.10	Form of Voting Agreement.	8-K	October 15, 2015	9.1	
9.20	Form of Voting Agreement.	8-K	July 6, 2016	9.1	
9.30	Form of Voting Agreement.	8-K	December 27, 2016	10.1	
10.1	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.	S-1/A	June 10, 2014	10.1	
10.2	1999 Incentive Stock Plan and forms of agreements thereunder.	S-1/A	June 10, 2014	10.2	
10.3	2010 Equity Incentive Plan and forms of agreements thereunder.	S-1/A	June 10, 2014	10.3	
10.4	2014 Equity Incentive Plan and forms of agreements thereunder.	S-1/A	July 1, 2014	10.4	
10.5	2014 Employee Stock Purchase Plan and forms of agreements thereunder.	S-1/A	July 1, 2014	10.5	
10.6	Offer Letter, dated June 22, 2007, by and between Soleno Therapeutics, Inc. and Ernest Mario, Ph.D.	S-1	June 10, 2014	10.6	
10.7	Employment Agreement, dated April 6, 2010, by and between Soleno Therapeutics, Inc. and Anish Bhatnagar.	S-1	June 10, 2014	10.7	
10.8	Offer Letter, dated May 29, 2013, between Soleno Therapeutics, Inc. and Anthony Wondka.	S-1	June 10, 2014	10.8	

Exhibit Number	Description of Document	Incorporated by Reference from Registrant's Form	Date Filed with the SEC	Exhibit Number	Filed Herewith
10.9	Offer Letter, dated April 17, 2014, by and between Soleno Therapeutics, Inc. and Antoun Nabhan.	S-1	June 10, 2014	10.9	
10.10	Asset Purchase Agreement dated May 11, 2010, by and between Soleno Therapeutics, Inc. and BioMedical Drug Development Inc.	S-1	June 10, 2014	10.10	
10.11	Convertible Note and Warrant Purchase Agreement, dated February 10, 2010, by and among Soleno Therapeutics, Inc. and the investors named therein.	S-1	June 10, 2014	10.11	
10.12	Amendment No. 1 to Convertible Note and Warrant Purchase Agreement, Convertible Promissory Notes and Warrants to Purchase Shares, dated November 10, 2010, by and among Soleno Therapeutics, Inc. and the investors named therein.	S-1	June 10, 2014	10.12	
10.13	Amendment No. 2 to Convertible Note and Warrant Purchase Agreement, Convertible Promissory Notes and Warrants to Purchase Shares, dated January 17, 2012, by and among Soleno Therapeutics, Inc. and the investors named therein.	S-1	June 10, 2014	10.13	
10.14	Convertible Note and Warrant Purchase Agreement, dated January 16, 2012, by and among Soleno Therapeutics, Inc. and the investors named therein.	S-1	June 10, 2014	10.14	
10.15	Omnibus Amendment to Convertible Note and Warrant Purchase Agreement, Convertible Promissory Notes and Warrants to Purchase Shares, dated July 31, 2012, by and among Soleno Therapeutics, Inc. and the investors named therein.	S-1	June 10, 2014	10.15	
10.16	Omnibus Amendment to Convertible Promissory Notes and Warrants to Purchase Shares, dated April 28, 2014, by and among Soleno Therapeutics, Inc. and the investors named therein.	S-1	June 10, 2014	10.16	
10.17	Convertible Note and Warrant Purchase Agreement, dated April 28, 2014, by and among Soleno Therapeutics, Inc. and the investors named therein.	S-1	June 10, 2014	10.17	
10.18	Omnibus Amendment to Convertible Note and Warrant Purchase Agreement, Convertible Promissory Notes and Warrants to Purchase Shares, dated May 5, 2014, by and among Soleno Therapeutics, Inc. and the investors named therein.	S-1	June 10, 2014	10.18	
10.19	Sublease, dated May 20, 2014, by and among Soleno Therapeutics, Inc. and Silicon Valley Finance Group.	S-1/A	July 1, 2014	10.19	
10.20	Offer Letter, dated June 24, 2014, by and between Soleno Therapeutics, Inc. and David D. O'Toole.	S-1/A	July 22, 2014	10.20	

Exhibit Number	Description of Document	Incorporated by Reference from Registrant's Form	Date Filed with the SEC	Exhibit Number	Filed Herewith
10.21	Loan Agreement by and between Soleno Therapeutics, Inc. and the investors named therein, dated September 29, 2014.	S-1/A	September 29, 2014	10.21	
10.22	Revised Second Tranche Closing Notice and Letter Amendment dated August 18, 2014 relating to the August 2014 Notes.	S-1/A	November 4, 2014	10.22	
10.23	Second Tranche Subsequent Closing Notice and Letter Amendment dated October 22, 2014 relating to the October 2014 Notes.	S-1/A	November 4, 2014	10.23	
10.24	Form of Warrant Exercise Agreement.	8-K	March 5, 2015	10.1	
10.25	Advisory Agreement by and between Soleno Therapeutics, Inc. and Maxim Group LLC, dated March 4, 2015.	S-4	April 1, 2015	10.25	
10.26	Agreement and First Amendment to Asset Purchase Agreement between the Company, BDDI and affiliate of BDDI, dated June 30, 2015.	8-K	July 7, 2015	10.1	
10.27	Common Stock Purchase Agreement between the Company and an affiliate of BDDI, dated June 30, 2015.	8-K	July 7, 2015	10.2	
10.28	Registration Rights Agreement between the Company and Aspire Capital Fund, LLC, dated July 24, 2015.	8-K	July 27, 2015	4.1	
10.29	Common Stock Purchase Agreement between the Company and Aspire Capital Fund, LLC, dated July 24, 2015.	8-K	July 27, 2015	10.1	
10.30	Engagement Letter dated September 17, 2015, between Soleno Therapeutics, Inc. and Maxim Group, LLC.	8-K	October 15, 2015	1.1	
10.31	Securities Purchase Agreement dated October 12, 2015.	8-K	October 15, 2015	10.1	
10.32	Form of Registration Rights Agreement.	8-K	October 15, 2015	10.2	
10.33	Form of Lock-Up Agreement.	8-K	October 15, 2015	10.3	
10.34	Amendment No. 1 to Securities Purchase Agreement dated October 29, 2015.	S-1/A	December 22, 2015	10.33	
10.35	Transfer and Distribution Agreement: United States: by and between Soleno Therapeutics, Inc. and Bemes, Inc. signed January 26, 2016.	8-K	January 28, 2016	10.1	
10.36	Engagement Letter dated June 26, 2016, between Soleno Therapeutics, Inc. and Maxim Group, LLC.	8-K	July 6, 2016	1.1	

Exhibit Number	Description of Document	Incorporated by Reference from Registrant's Form	Date Filed with the SEC	Exhibit Number	Filed Herewith
10.37	Securities Purchase Agreement dated June 29, 2016.	8-K	July 6, 2016	10.1	
10.38	Form of Registration Rights Agreement dated June 29, 2016.	8-K	July 6, 2016	10.2	
10.39	Amendment No. 1 to Securities Purchase Agreement dated September 20, 2016.	S-1/A	September 20, 2016	10.39	
10.40	Agreement and Plan of Merger and Reorganization, dated as of December 22, 2016, by and among Soleno Therapeutics, Inc., a Delaware corporation, Essentialis, Inc., a Delaware corporation, Company E Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of Soleno Therapeutics, and Neil Cowen as the stockholders' representative.	8-K	December 27, 2016	2.1	
10.41	Registration Rights Agreement between the Company and Aspire Capital Fund, LLC, dated January 27, 2017.	S-1	February 1, 2017	10.51	
10.42	Common Stock Purchase Agreement between the Company and Aspire Capital Fund, LLC, dated January 27, 2017.	S-1	February 1, 2017	10.52	
10.43	Stock Purchase Agreement made by and between the Company and NeoForce Holdings, Inc. a Delaware corporation dated July 18, 2017	8-K	July 24, 2017	2.1	
10.44	Joint Venture Agreement dated as of December 4, 2017 by and among Soleno Therapeutics, Inc., Capnia, Inc., and OptAsia Healthcare Limited	8-K	December 8, 2017	2.1	
10.45	Securities Purchase Agreement, dated as of December 11, 2017	8-K	December 13, 2017	10.1	
10.46	Confidential Consulting Agreement, dated September 5, 2017 by and between FLG Partners, LLC and the Company	8-K	June 4, 2018	10.1	
10.47	Securities Purchase Agreement, dated as of December 19, 2018	8-K	December 19, 2018	10.1	
10.48	Employment Agreement with Kristen Yen	S-1	March 29, 2019	10.48	
21.1	Subsidiaries				X
23.1	Consent of Marcum LLP				X
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended				X

Exhibit Number	Description of Document	Incorporated by Reference from Registrant's Form	Date Filed with the SEC	Exhibit Number	Filed Herewith
31.2	Certification of Principal Financial and Accounting Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended				X
32.1	Certification of Principal Executive Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350				X
32.2	Certification of Principal Financial and Accounting Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350				X
101.INS	XBRL Instance Document.				X
101.SCH	XBRL Taxonomy Extension Schema Document.				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.				X

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Soleno Therapeutics, Inc.

Date: March 4, 2020

By: /S/ ANISH BHATNAGAR
President and Chief Executive Officer

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Anish Bhatnagar, with full power of substitution and resubstitution and full power to act, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this annual report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/S/ ANISH BHATNAGAR Anish Bhatnagar	President, Chief Executive Officer and Director (Principal Executive Officer)	March 4, 2020
/S/ JAMES MACKANESS James Mackaness	Chief Financial Officer (Principal Financial and Accounting Officer)	March 4, 2020
/S/ ERNEST MARIO Ernest Mario	Chairman	March 4, 2020
/S/ ANDREW SINCLAIR Andrew Sinclair	Director	March 4, 2020
/S/ WILLIAM G. HARRIS William G. Harris	Director	March 4, 2020
/S/ STUART COLLINSON Stuart Collinson	Director	March 4, 2020
/S/ GWEN MELINCOFF Gwen Melincoff	Director	March 4, 2020
/S/ BIRGITTE VOLCK Birgitte Volck	Director	March 4, 2020

Exhibit 4.29

**DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES
EXCHANGE ACT OF 1934**

Soleno Therapeutics, Inc. (the "Company") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock, par value $0.001 per share.

As used in this summary, the terms "Soleno," "the Company," "we," "our" and "us" refer to Soleno Therapeutics, Inc.

The following is a description of the material terms and provisions relating to our common stock. The following description is a summary that is not complete and is subject to and qualified in its entirety by reference to our amended and restated certificate of incorporation and our amended and restated bylaws, and to provisions of the Delaware General Corporation Law. Copies of our amended and restated certificate of incorporation and our amended and restated bylaws, each of which may be amended from time to time, are included as exhibits to the Annual Report on Form 10-K to which this description is an Exhibit.

General

Our authorized capital stock consists of 110,000,000 shares, all with a par value of $0.001 per share, 100,000,000 of which are designated as Common Stock and 10,000,000 of which are designated Convertible Preferred Stock.

Common Stock

Holders of Common Stock are entitled to one vote per share on matters on which our stockholders vote. There are no cumulative voting rights. Subject to any preferential dividend rights of any outstanding shares of preferred stock, holders of Common Stock are entitled to receive dividends, if declared by our board of directors, out of funds that we may legally use to pay dividends. If we liquidate or dissolve, holders of Common Stock are entitled to share ratably in our assets once our debts and any liquidation preference owed to any then-outstanding preferred stockholders are paid. Our certificate of incorporation does not provide the Common Stock with any redemption, conversion or preemptive rights.

Anti-takeover provisions

Amended and Restated Certificate of Incorporation and Bylaws

Our amended and restated certificate of incorporation provides for our board of directors to be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, our stockholders holding a majority of the voting power of our shares of Common Stock outstanding will be able to elect all of our directors. The directors may be removed by the stockholders only for cause upon the vote of holders of a majority of the shares then entitled to vote at an election of directors. Furthermore, the authorized number of directors may be changed only by resolution of our board of directors, and vacancies and newly created directorships on our board of directors may, except as otherwise required by law or determined by our board, only be filled by a majority vote of the directors then serving on our board of directors, even though less than a quorum. Our amended and restated certificate of incorporation and amended and restated bylaws provide that all stockholder actions must be effected at a duly called meeting of stockholders and not by a consent in writing. A special meeting of stockholders may be called only by a majority of our whole board of directors, the chair of our board of directors, our chief executive officer or our president. Our amended and restated bylaws also provide that stockholders seeking to present proposals before a meeting of stockholders to nominate candidates for election as directors at a meeting of stockholders must provide timely advance notice in writing, and specify requirements as to the form and content of a stockholder's notice.

Our amended and restated certificate of incorporation further provides that the affirmative vote of holders of at least 66 2/3% of the voting power of all of the then outstanding shares of voting stock, voting as a single class, will be required to amend certain provisions of our certificate of incorporation, including provisions relating to the structure of our board of directors, the size of our board of directors, removal of directors, special meetings of stockholders, actions by written consent and cumulative voting. The affirmative vote of holders of at least 66 2/3% of the voting power of all of the then outstanding shares of voting stock, voting as a single class, will be required to amend or repeal our bylaws, although our bylaws may be amended by a simple majority vote of our board of directors; provided that any bylaw amendment adopted by our stockholders that specifies the votes necessary for the election of directors will not be further amended or repealed by our board of directors.

The foregoing provisions make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of our company by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change the control of our company.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of our company. These provisions are also designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy rights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in control of our company or our management. As a consequence, these provisions also may inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, or Section 203, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, our board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon closing of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned by: (i) persons who are directors and also officers; and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by our board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, pledge or other disposition of ten percent (10%) or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loss, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Limitation on Liability and Indemnification Matters

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, and may indemnify our employees and other agents, to the fullest extent permitted by the Delaware General Corporation Law, which prohibits our amended and restated certificate of incorporation from limiting the liability of our directors for the following:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our amended and restated certificate of incorporation does not eliminate a director's duty of care and in appropriate circumstances, equitable remedies, such as injunctive or other forms of non-monetary relief, remain available under Delaware law. This provision also does not affect a director's responsibilities under any other laws, such as the federal securities laws or other state or federal laws. Under our amended and restated bylaws, we will also be empowered to purchase insurance on behalf of any person whom we are required or permitted to indemnify.

In addition to the indemnification required in our amended and restated certificate of incorporation and amended and restated bylaws, we have entered into indemnification agreements with each of our current directors and officers. These agreements provide indemnification for certain expenses and liabilities incurred in connection with any action, suit, proceeding, or alternative dispute resolution mechanism, or hearing, inquiry, or investigation that may lead to the foregoing, to which they are a party, or are threatened to be made a party, by reason of the fact that they are or were a director, officer, employee, agent, or fiduciary of our company, or any of our subsidiaries, by reason of any action or inaction by them while serving as an officer, director, agent, or fiduciary, or by reason of the fact that they were serving at our request as a director, officer, employee, agent, or fiduciary of another entity. In the case of an action or proceeding by, or in the right of, our company or any of our subsidiaries, no indemnification will be provided for any claim where a court determines that the indemnified party is prohibited from receiving indemnification. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as we may provide indemnification for liabilities arising under the Securities Act to our directors, officers, and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the Securities Exchange and Commission, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

Transfer agent and registrar

The transfer agent and registrar for our Common Stock is American Stock Transfer & Trust Company, LLC.

Exhibit 21.1

Subsidiaries of Soleno Therapeutics, Inc.

Subsidiary	Jurisdiction
Soleno Therapeutics UK Ltd.	United Kingdom
Soleno Therapeutics Europe Ltd.	Ireland
Essentialis, Inc.	Delaware

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of Soleno Therapeutics, Inc. on Form S-8 (File Numbers 333-235999, 333-230402, 333-224070, 333-220056, 333-210563 and 333-200175) and Form S-3 (File Number 333-232068) of our report which includes an explanatory paragraph as to the Company's ability to continue as a going concern**,** dated March 4, 2020, with respect to our audits of the consolidated financial statements of Soleno Therapeutics, Inc. as of December 31, 2019 and 2018 and for each of the two years in the period ended December 31, 2019, which report is included in this Annual Report on Form 10-K of Soleno Therapeutics, Inc. for the year ended December 31, 2019.

/s/ Marcum LLP

Marcum LLP
San Francisco, CA
March 4, 2020

Exhibit 31.1

**CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER
PURSUANT TO
SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)**

I, Anish Bhatnagar, M.D., certify that:

1. I have reviewed this annual report on Form 10-K of Soleno 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(s) 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(s) 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 4, 2020

/S/ ANISH BHATNAGAR
Anish Bhatnagar
President, Chief Executive Officer
(principal executive officer)

Exhibit 31.2

**CERTIFICATION OF THE CHIEF FINANCIAL OFFICER
PURSUANT TO
SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)**

I, James Mackaness, certify that:

1. I have reviewed this annual report on Form 10-K of Soleno 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(s) 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(s) 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 4, 2020

/S/ JAMES MACKANESS
James Mackaness
Chief Financial Officer
(principal financial and accounting officer)

Exhibit 32.1

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Soleno Therapeutics, Inc. (the “Company”) on Form 10-K for the fiscal year ended December 31, 2019, as filed with the Securities and Exchange Commission (the “Report”), Anish Bhatnagar, President, Chief Executive Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- The information in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 4, 2020

/S/ ANISH BHATNAGAR
Anish Bhatnagar
President, Chief Executive Officer
(principal executive officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Soleno Therapeutics, Inc. (the “Company”) on Form 10-K for the fiscal year ended December 31, 2019, as filed with the Securities and Exchange Commission (the “Report”), James Mackaness, Chief Financial Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- The information in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 4, 2020

/S/ JAMES MACKANESS
James Mackaness
Chief Financial Officer
(principal financial and accounting officer)