As filed with the Securities and Exchange Commission on March 29, 2019

Registration No. 333-

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

FORM S-1
REGISTRATION STATEMENT
Under
The Securities Act of 1933

SOLENO THERAPEUTICS, INC.
(Name of registrant in its charter)

Delaware	3841	77-0523891
(State of Incorporation)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

1235 Radio Road, Suite 110
Redwood City, CA 94065
(650) 213-8444
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Anish Bhatnagar
Chief Executive Officer
Soleno Therapeutics, Inc.
1235 Radio Road, Suite 110
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(650) 213-8444
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Palo Alto, CA 94304
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Approximate date of proposed sale to the public: From time to time after this Registration Statement becomes effective.

If any securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box: ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company, or an emerging growth company. See 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 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price Per Security(2)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee
Common Stock, $0.001 par value	10,272,375	$2.32	$23,831,910	$2,889
Common Stock, $0.001 par value, underlying the warrants	513,617	$2.32(3)	$1,191,592	$145
Total			$25,023,502	$3,034

(1) Pursuant to Rule 416 under the Securities Act, there are also being offered an indeterminate number of additional securities as may from time to time become issuable by reason of stock splits, stock dividends, recapitalizations or other similar transactions.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c), calculated on the basis of the high and low prices of the registrant's Common Stock as reported on the NASDAQ Capital Market on March 26, 2019.

(3) Estimated solely for the purpose of the calculation of the registration fee pursuant to Rule 457(g), based on the exercise price of the warrants.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities, and the selling stockholders are not soliciting offers to buy these securities, in any state where the offer or sale of these securities is not permitted.

SUBJECT TO COMPLETION, DATED MARCH 29, 2019

PRELIMINARY PROSPECTUS

SOLENO THERAPEUTICS, INC.

Up to 10,785,992 Shares of common stock

This prospectus relates to the resale by the selling stockholders identified in this prospectus of up to an aggregate of 10,785,992 shares of our common stock, which consists of:

- up to 10,272,375 shares of our common stock that are issued and outstanding, or the Shares; and
- up to 513,617 shares, or the Warrant Shares, of our common stock that may be purchased upon exercise of issued and outstanding warrants, or the 2018 PIPE Warrants.

We refer to the Shares and the Warrant Shares collectively as the “2018 Resale Shares.” We sold the Shares and the 2018 Pipe Warrants to the selling stockholders in a private placement in December 2018, which we refer to as the 2018 PIPE Offering, pursuant to a Securities Purchase Agreement, which we refer to as the Unit Purchase Agreement.

The selling stockholders and any participating broker-dealers may be deemed to be “underwriters” within the meaning of the Securities Act of 1933, as amended, or the Securities Act, in connection with such sales. We will pay the expenses of registering these shares, but all selling and other expenses incurred by the selling stockholders will be paid by the selling stockholders.

Our common stock is listed on the NASDAQ Capital Market under the ticker symbol “SLNO.” On March 14, 2019, the last reported sale price per share of our common stock was $1.35 per share.

You should read this prospectus and any prospectus supplement, together with additional information described under the heading “Where You Can Find More Information,” carefully before you invest in any of our securities.

Investing in our securities involves a high degree of risk. See “Risk Factors” on page 5 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

This prospectus is dated , 2019.

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You should rely only on the information contained in this prospectus or any prospectus supplement or amendment thereto. We have not authorized anyone to provide you with different information.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before deciding to invest in our securities, you should read this entire prospectus carefully, including the sections of this prospectus entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes contained elsewhere in this prospectus. Unless the context otherwise requires, references in this prospectus to the "Company," "Soleno Therapeutics," "we," "us", and "our" refer to Soleno Therapeutics, Inc.

Company Overview

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 has tested Diazoxide Choline Controlled Release tablets, or DCCR, as a treatment for Prader-Willi Syndrome, or 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.

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 hydrolyzed to diazoxide prior to absorption. Diazoxide acts by stimulating ion flux through ATP-sensitive K^+ channels (K_{ATP}). The KATP channel links the cellular energy status to the membrane potential. 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 hyperphagia, which is an insatiable desire to eat. Agonizing the channel in GABAergic neurons improves GABA signaling and may reduce aggressive behaviors.

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 in the approved indications. In addition to the short-term use (<3 months) in the approved indications for Proglycem, there are also extensive data on chronic use in children with congenital hyperinsulinism, or CI, and in adults with insulinoma. Insulinoma patients tend to be older, with 50% of them over 70 years old. Published data have reported the average duration of use of Proglycem in CI 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 that lowers peak plasma concentration compared to diazoxide oral suspension and slows release of diazoxide from DCCR, making it suitable for once-a-day dosing. The control of release and absorption of diazoxide achieved using DCCR results in stable and consistent intraday circulating drug levels, and likely, consistent levels of diazoxide in tissues that are the site of action of the drug (the hypothalamus). In circulation, diazoxide is extensively protein bound. Only unbound diazoxide is active. The consistent absorption of diazoxide may also result in some level of disequilibrium in protein binding, potentiating the therapeutic response to treatment. The controlled rate of absorption, level intraday circulating drug levels and the disequilibrium in protein binding likely results in the potential for improved therapeutic response to treatment. 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 to 1 in 25,000 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. In addition, 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 and destroying property, throwing temper tantrums and directing rage or anger at others.

PWS is typically thought of as a genetic obesity, which is often significant. With increasing awareness among families and caregivers leading to significant control of food intake, many PWS patients today may not be obese. However, they 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. The reported rates of psychotic symptoms, between 6% and 28%, are higher than those for individuals with other intellectual disabilities. 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.

Clinical Trial of DCCR for PWS

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. On March 14, 2019, the Data Safety Monitoring Board (DSMB) recommended the continuation of the 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 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.

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 an 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.

Risks Associated With Our Business

Our business is subject to numerous risks and uncertainties related to the development and commercialization of DCCR, our joint venture involving CoSense, our reliance on third parties for manufacturing, our financial condition and need for additional capital, the operation of our business, our intellectual property, government regulation and ownership of our securities. These risks include those highlighted in the section entitled "Risk Factors" immediately following this prospectus summary, including the following:

- We are primarily a clinical-stage company with no approved products, which makes assessment of our future viability difficult.
- We are significantly dependent upon the success of DCCR, our sole therapeutic product candidate.
- 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.
- If we fail to obtain regulatory approval for DCCR in the U.S. and E.U., our business would be harmed.
- 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.
- 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.
- 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.
- 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.
- 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 the market opportunity for DCCR is smaller than we believe it is, then our revenues may be adversely affected, and our business may suffer.
- Our patent rights may prove to be an inadequate barrier to competition.

Corporate information

We were incorporated in Delaware in August of 1999. Our principal executive offices are located at 1235 Radio Road, Suite 110, Redwood City, CA 94065, and our telephone number is (650) 213-8444. Our website address is www.soleno.life. The information contained on our website is not incorporated by reference into this prospectus, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus, or in deciding whether to purchase our securities.

The Offering

Common stock being offered by the selling stockholders	10,785,992 shares
Selling stockholders	Abingworth Bioventures VII, LP, Mario 2002 Grandchildren's Trust, Mildred M. Mario Fifteen Year Residence Trust, Jack W. Schuler Living Trust, JS Grandchildren Trust, Schuler Descendants Trust, Tino Hans Schuler Trust, Therese Heidi Schuler Trust, Tanya Eva Schuler Trust, Schuler Grandchildren LLC, Oracle Partners, L.P., Oracle Ten Fund, L.P. Oracle Institutional Partners, L.P.
Common stock outstanding	31,755,169 (as of March 14, 2019)
Use of proceeds	The selling stockholders will receive all of the proceeds from the sale of the shares offered for sale by them under this prospectus. We will not receive proceeds from the sale of the shares by the selling stockholders.
NASDAQ Symbol	SLNO
Risk Factors	Investing in our securities involves a high degree of risk. You should carefully review and consider the "Risk Factors" section of this prospectus for a discussion of factors to consider before deciding to invest in shares of our common stock.

The number of shares of our common stock outstanding excludes 2,120,007 shares of our common stock issuable upon exercise of outstanding stock options, 921,849 shares of our common stock available for future issuance under the stock option plans, outstanding warrants exercisable for 120,421 shares of our common stock, 485,121 shares of our common stock issuable upon exercise of our outstanding Series A Warrants, 118,083 shares of our common stock issuable upon exercise of our outstanding Series C Warrants, 586,162 shares of our common stock issuable upon exercise of our outstanding Series D Warrants, 6,024,425 outstanding warrants from the 2017 PIPE Offering and 513,617 outstanding warrants from the 2018 PIPE Offering, each of which securities are outstanding or available for issuance as of March 14, 2019.

Sale of the Units to the Selling Stockholders

On December 19, 2018, we entered into a Securities Purchase Agreement, or the Unit Purchase Agreement, with the selling stockholders pursuant to which we sold and issued 10,272,375 immediately separable units at a price per unit of $1.60625 for aggregate gross proceeds of approximately $16,500,000 Each unit consisted of one share of our common stock and a warrant to purchase 0.05 of a share of our common stock at an exercise price of $2.00 per share, for an aggregate of 10,272,375 shares of our common stock, or the Shares, and corresponding warrants, or the 2018 PIPE Warrants, to purchase 513,617 shares of our common stock, or the Warrant Shares. We refer to the Shares and the Warrant Shares collectively as the Resale Shares. We also granted certain registration rights to the selling stockholders pursuant to the Unit Purchase Agreement pursuant to which, among other things, we are preparing and filing this registration statement with the SEC to register for resale the Resale Shares.

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 our Annual Report on Form 10-K and our Quarterly Report on Form 10-Q, 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 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 and medical devices 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, 2018, we had an accumulated deficit of $127.0 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 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, 2018, we have incurred significant operating losses since inception and continue to generate losses from operations and have an accumulated deficit of $127.0 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, 2018, our cash balance was $23.1 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 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. As of March 26, 2019 we are aware of seven 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, Jonathan Wolter, our Chief Financial Officer, 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. 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.

With respect to our joint venture, the accuracy of CoSense depends, in part, on the function of proprietary software run by the microprocessors embedded in the device, and despite our efforts to test the software extensively, it is potentially subject to malfunction, 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.

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, 2018, we had nine employees and fourteen 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. These are particularly stringent in California, including for purposes of our joint venture with OAHL, where the Cosense manufacturing facility and several suppliers are located. 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. With respect to our joint venture, the current clearance for CoSense, as well as any additional regulatory approval that we receive for any of our other planned products may be subject to limitations on the indicated uses for which the product may be marketed. 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. Our joint venture has obtained a CE Mark certification for CoSense and it is therefore authorized for sale in the E.U.; however, in order to market products in Asia, Latin America and other foreign jurisdictions, we must obtain separate regulatory approvals.

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 and CE Mark certification does not ensure approval by regulatory authorities in other countries, 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:

- imposes a tax of 2.3% on the retail sales price of medical devices sold after December 31, 2012;
- 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 PPACA, among other things, imposed an excise tax of 2.3% on the sale of most medical devices, including ours, and any failure to pay this amount could result in the imposition of an injunction on the sale of our products, fines and penalties. Although this tax has been suspended through 2019, it is expected to apply to sales of our products, including CoSense devices and may be applicable to CoSense consumables sold under our joint venture and also Serenz devices, in 2020 and thereafter. 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 device 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 this offering and 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, 2018, through December 31, 2018, the reported high and low prices of our common stock ranged from $3.60 to $1.45. 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:

- our ability to successfully commercialize, and realize significant revenues from sales of our products;
- the success of competitive products or technologies;
- the results of 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.

We issued 13,780 shares of Series B Convertible Preferred Stock in 2017. As of December 31, 2017, all of the shares of Series B Convertible Preferred Stock have been converted into 2,556,000 shares of common stock. Under the terms of the Series B Convertible Preferred Stock, no shares of common stock have been issued to Sabby Management, LLC, or "Sabby", upon conversion of the Series B Convertible Preferred Stock to the extent such issuance of shares of common stock would have resulted in Sabby having ownership in excess of 4.99%.

On March 7, 2017, we issued 1,666,666 shares of common stock for an investment of $8.0 million from the completion of the concurrent financing and issued 416,666 shares of common stock for an investment of $2.0 million from Aspire Capital pursuant to the 2017 Aspire Purchase Agreement. All the shares issued under the 2017 Aspire Purchase Agreement are eligible for future resale under a registration statement on Form S-1 on February 1, 2017 that was declared effective by the SEC on February 15, 2017. We terminated the 2017 Aspire Purchase Agreement on December 15, 2017 in connection with the closing of the 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.

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 agreed to prepare and file with the SEC a registration statement to register for resale the 2018 Resale Shares prior to March 31, 2019.

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.

We are an "emerging growth company," and a "smaller reporting company" and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, which was enacted in April 2012, and as a "smaller reporting company" under the Exchange Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. After we are no longer an emerging growth company and for as long as we remain a smaller reporting company, we will remain eligible for certain exemptions, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation, but we will be required to hold a nonbinding advisory vote on executive compensation and obtain stockholder approval of golden parachute payments.

We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering, or IPO, which would be December 31, 2019, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, (3) the date on which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. We will remain a smaller reporting company until we have a public float, or value attributable to stock held by non-affiliates, of at least $250 million, as measured on the prior June 30th.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use the extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period under the JOBS Act.

We cannot predict if investors will find our common stock less attractive to the extent we rely on available exemptions. If some investors do find our common stock less attractive, there may be a less active trading market for our common stock and our stock price may be more volatile or may decline.

Our executive officers, directors and principal stockholders have significant voting power and may take actions that may not be in the best interest of our other stockholders.

As of March 14, 2019, our executive officers, directors and each stockholder holding 5% or more of our outstanding common stock and their affiliates own 84.26% of our outstanding common stock in the aggregate, without giving effect to the sale of shares by any such persons in this offering. 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. In addition, we will be required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting beginning with our annual report on Form 10-K following the date on which we are no longer an emerging growth company or smaller reporting company. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. 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, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, 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 and to obtain an unqualified report on internal controls from our auditors as required under Section 404. 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 A, Series C, 2017 PIPE Warrants and 2018 PIPE Warrants in cash.

If, at any time while the Series A, 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 and Series A Warrants 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 A Warrants may exercise their right to acquire the common stock and pay an exercise price of $32.50 per share prior to the expiration of the five-year term on November 12, 2019, after which date any unexercised Series A Warrants will expire and have no further value. 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 A Warrants, 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.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein, contain forward-looking statements regarding management's expectations, beliefs, strategies, goals, outlook and other non-historical matters. In some cases you can identify these statements by forward-looking words, such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "could,""would," "project," "plan," "potential," "seek," "expect," "goal," or the negative or plural of these words or similar expressions.

These forward-looking statements include, but are not limited to, statements concerning the following:

- the timing and the success of additional approvals of any of our products pursuant to our clinical and regulatory efforts;
- our ability to successfully build a distribution network and commercial infrastructure for our products;
- whether the results of the trials will be sufficient to support domestic or global regulatory approvals for any of our products;
- our ability to obtain and/or maintain regulatory approval of our products;
- our expectation that our existing capital resources will be sufficient to enable us to successfully meet the capital requirements for all of our current and future products;
- the benefits of the use of our products;
- the projected dollar amounts of future sales of established and novel diagnostics for neonatal hemolysis;
- our ability to successfully commercialize any products;
- the rate and degree of market acceptance of our products;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to manufacture our products in conformity with the applicable regulatory requirements and to scale up manufacturing of our products to commercial scale;
- our ability to compete with companies that may enter the market with products that compete with our products;
- our reliance on third parties to conduct clinical studies;
- our reliance on third-party contract manufacturers to manufacture and supply our products for us;
- our reliance on our collaboration partners' performance over which we do not have control;
- our ability to retain and recruit key personnel, including development of a sales and marketing function;
- our ability to obtain and maintain intellectual property protection for our products;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing;
- our expectations regarding the time during which we will be an emerging growth company under the Jobs Act;
- our ability to identify, develop, acquire and in-license additional products;
- our ability to successfully establish and successfully maintain appropriate collaborations and derive significant revenue from those collaborations;
- our financial performance; and
- developments and projections relating to our competitors or our industry.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in "Risk Factors" herein. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

USE OF PROCEEDS

We will not receive any proceeds upon the sale of the Resale Shares by the selling stockholders.

MARKET INFORMATION FOR OUR COMMON STOCK AND DIVIDEND POLICY

Market Information

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

As of March 6, 2019, there were 80 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.

SELECTED FINANCIAL DATA

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.

YEARS ENDED DECEMBER 31, 2018 AND 2017

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 prospectus. This prospectus 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,” prospectus and elsewhere in this prospectus. The forward-looking statements in this prospectus represent our views as of the date of this prospectus. 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 prospectus.

Business Overview

We were initially established 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 December 22, 2016, we entered into the Merger Agreement 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 U.S. as well as in the E.U. Consummation of the Merger was subject to various closing conditions, including our consummation of a financing of at least $8.0 million at, or substantially contemporaneous with, the closing of the Merger, which occurred on March 7, 2017 and the receipt of stockholder approval of the Merger at a special meeting of our stockholders, which was held on March 6, 2017. As a result, we now primarily focus on the development and commercialization of novel therapeutics for the treatment of rare diseases. Our current research and development efforts are primarily focused on advancing our lead candidate, DCCR tablets for the treatment of PWS, into late-stage clinical development.

Subsequent to March 7, 2017, we explored opportunities, and made a decision to divest, sell or otherwise dispose of the CoSense, NFI and Serenz businesses. Accordingly, and pursuant to ASC 205-20-45-10, the assets and liabilities related to the discontinued activities of CoSense, NFI and Serenz businesses are presented separately in the balance sheet as held for sale items, and the related operations reported herein for the CoSense, NFI and Serenz activities are reported as discontinued operations in the statements of operations until the time that the assets were disposed of. Our remaining ownership in Capnia is recorded as an investment and initially measured at fair value.

Our previously wholly-owned subsidiary NFI also marketed innovative pulmonary resuscitation solutions for the inpatient and ambulatory neonatal markets. We sold NFI in a stock transaction that was completed on July 18, 2017, pursuant to the NFI Purchase Agreement with Neoforce Holdings, a wholly-owned subsidiary of Flexicare Medical Limited, a privately-held United Kingdom company, for $720,000 and adjustments for inventory and the current cash balances held at NFI (see Note 5).

On December 4, 2017, we and our then wholly-owned subsidiary Capnia, entered into a joint venture with 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 hold a controlling interest in Capnia. Accordingly, we deconsolidate Capnia’s financial statements from ours and our remaining minority interest in Capnia is reported as a Minority interest investment in our consolidated balance sheet.

We continue to separately evaluate alternatives for our Serenz portfolio.

On July 27, 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, 2018, we had an accumulated deficit of $127.0 million, primarily as a result of research and development and general and administrative expenses. While we may in the future generate revenue from a variety of sources, potentially including sales of our neonatology products, therapeutic products, other diagnostic products, license fees, milestone payments, and research and development payments in connection with potential future strategic partnerships, we have, to date, generated approximately $2,000 of revenue only from the 2013 license agreement pertaining to Serenz, approximately $2.7 million in revenue from our neonatology products and approximately $0.2 million in government grants; these activities are reported as discontinued operations in our accompanying consolidated financial statements. We may never be successful in commercializing our novel therapeutic and in divesting, selling or otherwise disposing of our existing neonatology products or related therapeutic products. 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.

Financings

Sabby 2016 Stock Purchase

We issued a total of 13,780 780 shares of Series B Convertible Preferred Stock under the Securities Purchase Agreement entered into on June 29, 2016 with Sabby Healthcare Master Fund Ltd and Sabby Volatility Warrant Fund Ltd, which are funds managed by Sabby Management, LLC, collectively referred to as Sabby, as amended by Amendment No. 1 dated September 2016, referred to as the 2016 Sabby Purchase Agreement. These shares had a par value of $0.001 and a stated value of $1,000 per share. The aggregate purchase price of the Series B Convertible Preferred shares was $13.8 million, and were convertible to common stock at a rate of 200 shares of common stock for each converted share of Series B Convertible Preferred Stock, for a total of 2,756,000 shares of our common stock, based on a fixed conversion price of $5.00 per share on an as-converted basis. Under the terms of the Series B Convertible Preferred Stock, in no event shall shares of common stock be issued to Sabby upon conversion of the Series B Convertible Preferred Stock to the extent such issuance of shares of common stock would result in Sabby having ownership in excess of 4.99%. The Series B Convertible Preferred Stock did not have an expiration date and were not redeemable at the option of the holders. In addition, on the effect date of the 2016 Sabby Purchase Agreement the exercise price of the existing Series D Warrants originally issued in conjunction with the 2015 Sabby Purchase Agreement was reduced from $12.30 to $8.75 per share. In connection with the 2016 Sabby Purchase Agreement, we also were obligated to repurchased the remaining 7,780 outstanding Series A Convertible Preferred Stock held by Sabby for an aggregate amount of $7.8 million, which shares were originally purchased by Sabby under the 2015 Sabby Purchase Agreement and which shares represent 841,081 shares of common stock on an as-converted basis. The sale of the Series B Convertible Preferred Stock occurred in two separate closings. The first closing was on July 5, 2016 and the second closing was on September 29, 2016. Between the two closings, after the repurchase of the Series A Convertible Preferred Stock and estimated transaction expenses, we received $5.6 million of net proceeds. During 2016, 2017 and 2018 Sabby converted 1,000, 8,209 and 4,571 shares of Series B Convertible Preferred stock into 200,000, 1,641,800 and 914,200 shares of common stock, respectively. As of December 31, 2018, there were no shares of Series B Convertible Preferred Stock outstanding.

Aspire Stock Purchase

On January 27, 2017, we entered into a Common Stock Purchase Agreement (the “2017 Aspire Purchase Agreement”) with Aspire Capital Fund, LLC (“Aspire Capital”), which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $17.0 million in value of shares of our common stock over the 30-month term of the 2017 Aspire Purchase Agreement. We issued Aspire Capital 141,666 shares of common stock as commitment shares under the 2017 Aspire Purchase Agreement. The 2017 Aspire Purchase Agreement was terminated upon the closing of the 2017 PIPE Offering.

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 agreed to prepare and file with the SEC a registration statement to register for resale the 2018 Resale Shares prior to March 31, 2019.

Financial overview

Summary

We have not generated net income from operations to date, and, at December 31, 2018 and December 31, 2017, we had an accumulated deficit of $127.0 million and $113.7 million, respectively, 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, Neo Force, Inc. 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, Neo Force, Inc. 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, Neo Force, Inc. 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, Neo Force, Inc. 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 and changes in the fair value of the Series A, Series C and 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.

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 granted to employees and directors are measured at the date of grant based on the estimated fair value of the award. We estimate the grant date fair value, 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 we grant to employees 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 volatilities of common stock of 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.

Business combinations

Business combinations are recorded in accordance with ASC 805. Business combinations are considered, pursuant to ASC 805, to be a purchase of a business entity or a purchase of assets. The guidance established by ASU 2017-01 provides additional guidance in assessing the purchase by providing an initial screen to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single asset or group of similar assets; if the substance of this test is met, the acquisition is treated as a purchase of assets and not the acquisition of a business entity.

Our acquisition of Essentialis was determined to be an asset acquisition, and the total value of the purchase consideration was allocated to the asset acquired. The asset acquired was recorded as the sum of the estimated fair value of the shares issued on the completion of the merger, the estimated fair value of the shares to be issued under the holdback and milestone stock payment provisions in the future, the estimated fair value of the contingent consideration to be paid for achieving certain commercial milestones in the future, and the value equivalent to the increase in the liability for deferred taxes resulting from the tax effect of the net assets and liabilities acquired.

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 the 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.

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, 2018 and 2017 from continuing operations

	Year Ended December 31,		Increase (decrease)	
	2018	2017	Amount	Percentage
	(in thousands)			
Operating expenses:				
Research and development	$ 7,178	$ 3,069	$ 4,109	134%
Sales and marketing	—	26	(26)	100%
General and administrative	6,556	6,584	(28)	0%
Change in fair value of contingent consideration	567	2,492	(1,925)	77%
Total operating expenses	14,301	12,171	2,130	18%
Operating loss	(14,301)	(12,171)	(2,130)	18%
Other income (expense)				
Cease-use income	6	4	2	50%
Change in fair value of warrants liabilities	522	(685)	1,207	176%
Gain on deconsolidation of former subsidiary	1,994	—	1,994	n/a
Interest and other expense, net	(62)	(590)	528	89%
Total other income (expense)	2,460	(1,271)	3,731	294%
Loss from continuing operations before provision for tax benefit	(11,841)	(13,442)	1,601	12%
Provision for tax benefit	—	1,650	(1,650)	100%
Loss from continuing operations	(11,841)	(11,792)	(49)	0%
Loss from discontinued operations	(1,494)	(3,593)	2,099	58%
Net loss	$ (13,335)	$ (15,385)	$ 2,050	13%

Revenue

We have not commenced commercialization of DCCR, our current sole novel therapeutic product, and accordingly, through December 31, 2018, have generated no revenue in continuing operations.

Research and development expense

Research and development expense of $7.2 million for the year ended December 31, 2018 increased by $4.1 million over 2017 resulting primarily from efforts directed toward development and commencement, during the quarter ended June 30, 2018, of the Phase III trial of DCCR which we acquired with the Essentialis acquisition on March 7, 2017.

Sales and marketing expense

Sales and marketing expense of approximately $26,000 during 2017 consisted of expense incurred to revise our website. We have not yet commenced commercialization of DCCR, our current sole novel therapeutic product, and accordingly, during 2018 have incurred no sales and marketing activities in continuing operations.

General and administrative expense

General and administrative expense of $6.6 million during 2018 decreased by approximately $28,000 from 2017. The decrease was primarily due to planned spending reductions in 2018, specifically including a decrease in employee and consultant-related expenses of approximately $329,000, approximately $275,000 of general cost savings including the sublease of excess facility space, and an approximate $71,000 reduction in legal costs related to our intellectual property. These decreases were largely offset by approximately $355,000 of additional amortization expense of the intangible patent asset acquired in the March 7, 2017 acquisition of Essentialis, as 2017 had amortization for a portion of the year compared to the entire period in 2018, and an increase of approximately $288,000 for professional fees and investor communication expenses, primarily related to financing activities and regulatory filings required in 2018

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 $5.6 million as of December 31, 2018, an approximate $567,000 increase from the estimate as of December 31, 2017. During 2017 the estimate increased $2.5 million from the initial liability of $2.6 million estimated at the time of the merger.

Other income (expense)

Other income of approximately $2.5 million in 2018 increased $3.7 million from other expense of $1.3 million during 2017. The increase in other income was primarily due to a $2.0 million gain recognized on the deconsolidation of Capnia upon the issuance of majority shares to OAHL and a net decrease in the fair value of warrants liabilities during 2018 compared to a net increase in 2017, resulting in a net increase of $1.2 million. In addition, there was an approximate $528,000 decrease in interest and other expense due primarily to the fact that during 2017 there were commitment shares issued to Aspire Capital with a value of approximately $600,000.

Results of Discontinued Operations

Discontinued operations 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,		Increase (decrease)	
	2018	2017	Amount	Percentage
	(in thousands)			
Product revenue	$ 62	$ 735	$ (673)	92%
Cost of product revenue	32	820	(788)	96%
Gross profit (loss)	30	(85)	115	135%
Expenses:				
Research and development	1,106	2,427	(1,321)	54%
Sales and marketing	25	218	(193)	89%
General and administrative	393	669	(276)	41%
Total expenses	1,524	3,314	(1,790)	54%
Operating loss	(1,494)	(3,399)	1,905	56%
Other expense				
Loss on sale of assets	—	(186)	186	100%
Other expense	—	(8)	8	100%
Total other expense	—	(194)	194	100%
Net loss from discontinued operations	$ (1,494)	$ (3,593)	$ 2,099	58%

Product revenue

Revenue related to our discontinued operations was approximately $62,000 during 2018, an approximate $673,000 decrease from the discontinued operations revenue during 2017. The decrease resulted primarily from the sale of the NFI business in July 2017 and a decrease in Capnia revenue.

Cost of product revenue

Cost of product revenue related to our discontinued operations has declined in relation to the decrease in sales activity.

Research and development expense

Research and development expense related to our discontinued operations decreased by $1.3 million from 2017 to 2018. The decrease primarily resulted from the sale of NFI in July 2017, and the curtailment of spending towards the development of the Serenz product during 2017.

Sales and marketing expense

Sales and marketing expense during 2018 was approximately $25,000, representing an approximate $193,000 decrease from 2017. The decrease is largely attributed to our stopping the promotion and sales of the Serenz product in the second quarter of 2017. The sales and marketing expenses relating to our discontinued operations during 2018 relate only to Capnia's marketing of its CoSense products.

General and administrative expense

General and administrative expense associated with our discontinued operations was approximately $393,000 during 2018, a decrease of approximately $276,000 from 2017. The decrease was primarily due to the sale of NFI in July 2017.

Other expense

During 2017 we recorded other expense of approximately $194,000, consisting primarily of the loss recorded on the sale of our wholly-owned subsidiary, NFI.

Liquidity and Capital Resources

We had a net loss of $13.3 million during 2018 and an accumulated deficit of $127.0 million at December 31, 2018 from having incurred losses since our inception. We had $22.8 million of working capital at December 31, 2018 and used $11.7 million of cash in operating activities during 2018. We have financed our operations principally through issuances of equity securities.

We have continued to focus on expense control, including reducing our workforce, eliminating outside consultants, reducing legal fees and implementing a plan to allow Board members to receive common stock, in lieu of cash payments.

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.

We expect to continue incurring losses for the foreseeable future and may 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 prospectus. 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.

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, 2018	Year Ended December 31, 2017
	(in thousands)	
Net cash used in continuing operating activities	$ (10,322)	$ (6,919)
Net cash used in discontinued operating activities	(1,361)	(3,031)
Net cash used in operating activities	(11,683)	(9,950)
Net cash used in continuing investing activities	(8)	(562)
Net cash (used in) provided by discontinued investing activities	(172)	716
Net cash (used in) provided by investing activities	(180)	154
Net cash provided by continuing financing activities	16,302	23,945
Net cash provided by discontinued financing activities	1,525	225
Net cash provided by financing activities	17,827	24,170
Net increase (decrease) in cash, cash equivalents and restricted cash		
Continuing operations	5,972	16,464
Discontinued operations	(8)	(2,090)
Net increase in cash, cash equivalents and restricted cash	$ 5,964	$ 14,374

Continuing Operations

Cash used in operating activities

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, $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.

During the year ended December 31, 2017, we used net cash of $6.9 million for continuing operating activities, resulting primarily from the loss from continuing operations of $11.8 million, adjusted for the non-cash items consisting primarily of $1.6 million of depreciation and amortization, $2.5 million of expense for the change in the fair value of contingent consideration for the acquisition of Essentialis, $1.2 million of expenses paid with common stock or equity awards, approximately $602,000 for issuing shares to Aspire Capital, and approximately $685,000 for the change in fair value of the liability for warrants, all of which were partially offset by the non-cash provision for income tax benefit in the amount of $1.7 million.

Cash used in investing activities

Minimal cash was used for investing activities during 2018 and 2017 for the costs of acquiring property and equipment. During 2017 the net cash used in investing activities was primarily a result of approximately $573,000 for the payment of costs associated with the acquisition of Essentialis.

Cash provided by financing activities

During 2018 we obtained $16.5 million of cash from the issuance of common stock and warrants in the 2018 PIPE Offering, which proceeds were partially offset by approximately $250,000 of costs. During 2017 we obtained net cash of $23.9 million resulting from the proceeds of $10.0 million from the issuance of common stock immediately upon closing the acquisition of Essentialis together with $15.0 million of proceeds from the issuance of common stock and warrants on common stock resulting from the 2017 PIPE Offering, all of which proceeds were partially offset by $1.1 million of costs paid for the raising and issuance of the related securities offerings.

As of December 31, 2018, we had cash, cash equivalents and restricted cash of $23.1 million.

We do not believe that we 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 may 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

During 2018 we used net cash of $1.4 million for discontinued operating activities, compared to $3.0 million during 2017. The decrease was primarily due to the lower comparative level of operating activities for the discontinued operations, reflecting primarily the sale of NFI in July 2017, and to a lesser extent the deconsolidation of Capnia, Inc. upon the transfer of the majority share ownership in October 2018.

Cash provided by (used in) investing activities

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. During 2017 net cash provided by investing activities was approximately $716,000, resulting primarily from the sale of the NFI operations in July 2017.

Cash provided by financing activities

Net cash provided by financing activities related to discontinued operations was $1.5 million during 2018 and approximately $225,000 during 2017, representing the cash received during the respective periods from our joint venture partner.

Contractual Obligations and Commitments

As of December 31, 2018, we had lease obligations totaling approximately $335,000, consisting of operating leases for our operating facilities in Redwood City, California. We signed a lease for our current operating facilities at 1235 Radio Road in Redwood City in July 2015, which expires in August of 2019. We are subleasing a portion of this unused space to two separate parties.

The following table summarizes our contractual obligations as of December 31, 2018 (in thousands).

	Payments due by period				
	Less than 1 year	1 to 3 years	4 to 5 years	After 5 years	Total
Lease obligations	$ 335	$ —	$ —	$ —	$ 335
Total	$ 335	$ —	$ —	$ —	$ 335

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, 2018, 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 of the Financial Statements).

BUSINESS

Company Overview

We were incorporated in the State of Delaware on August 25, 1999, and are located in Redwood City, California. On May 8, 2017, we received stockholder approval to amend our Amended and Restated Certificate of Incorporation to change our name from "Capnia, Inc." to "Soleno Therapeutics, Inc." 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.

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 has tested Diazoxide Choline Controlled Release tablets, or DCCR, as a treatment for Prader-Willi Syndrome, or 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, 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 hydrolyzed to diazoxide prior to absorption. Diazoxide acts by stimulating ion flux through ATP-sensitive K+ channels (K_{ATP}). The K_{ATP} channel links the cellular energy status to the membrane potential. Diazoxide appears to act on signs and symptoms of PWS in a variety of ways. Agonizing the K_{ATP} channel in the hypothalamus has the potential to address hyperphagia, which is an insatiable desire to eat. Agonizing the channel in GABAergic neurons improves GABA signaling and may reduce aggressive behaviors.

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 in the approved indications. In addition to the short-term use (<3 months) in the approved indications for Proglycem, there are also extensive data on chronic use in children with congenital hyperinsulinism, or CI, and in adults with insulinoma. Insulinoma patients tend to be older, with 50% of them over 70 years old. The average duration of use of Proglycem in CI 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 that lowers peak plasma concentration compared to diazoxide oral suspension and slows release of diazoxide from DCCR, making it suitable for once-a-day dosing. The control of release and absorption of diazoxide achieved using DCCR results in very level and consistent intraday circulating drug levels, and consistent levels of diazoxide in tissues that are the site of action of the drug (the hypothalamus). In circulation, diazoxide is extensively protein bound. Only unbound diazoxide is active. The consistent absorption of diazoxide may also result in some level of disequilibrium in protein binding, potentiating the therapeutic response to treatment. The controlled rate of absorption, level intraday circulating drug levels and the disequilibrium in protein binding likely results in the potential for improved therapeutic response to treatment. 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 to 1 in 25,000 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 and destroying property, throwing temper tantrums and directing rage or anger at others.

PWS is typically thought of as a genetic obesity, which is often significant. With increasing awareness among families and caregivers leading to significant control of food intake, many PWS patients today may not be obese. However, they 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. The reported rates of psychotic symptoms, between 6% and 28%, are higher than those for individuals with other intellectual disabilities. 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. 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 Trial of DCCR for PWS

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.

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 an 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 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.

Safety of DCCR in the Treatment of PWS

Many of the adverse events 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 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 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. Its estimated incidence is 1:15,000 to 1:25,000 live births and is present in all races and ethnicities. 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. We anticipate that DCCR could be the first effective treatment for hyperphagia in PWS to reach the market both in the U.S. and Europe and would 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 typically 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., Zafgen, Inc., Rhythm Pharmaceuticals, Inc., Saniona AB, Insys Therapeutics, Inc., 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, and 9,782,416) 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 a number of aspects of 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 each drug, we obtain FDA approval of the manufacturing facilities for companies who manufacture our drugs for us. 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 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 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. The self-referral laws may cause some physicians who would otherwise use our laboratory to use other laboratories for their testing.

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 and as a result of this investment, when made, Capnia would no longer be our wholly-owned subsidiary. Going forward, OAHL would be responsible for funding the operations of Capnia. In addition, OAHL has the option to buy our remaining interest in Capnia as set forth in the Joint Venture Agreement.

During 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 is classified as an equity method investment.

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 agreed to prepare and file with the SEC a registration statement to register for resale the 2018 Resale Shares prior to March 31, 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.

Employees

As of December 31, 2018, we had nine full-time employees and fourteen 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 1235 Radio Road, Suite 110, 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.

DESCRIPTION OF PROPERTIES

Our principal facilities consist of office space in Redwood City, California, which also contains space for Capnia's final assembly and calibration facility for CoSense. We currently occupy 8,171 square feet of office space under a non-cancelable operating lease that terminates in August 2019.

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.

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.

MANAGEMENT

Directors and Executive Officers

The following table sets forth information regarding our executive officers and directors as of March 14, 2019:

Name	Age	Position
Executive Officers:		
Anish Bhatnagar, M.D.	51	President, Chief Executive Officer and Director
Jonathan Wolter	68	Chief Financial Officer
Kristen Yen	50	Vice President of Clinical Operations
Non-Employee Directors:		
Ernest Mario, Ph.D.(2)	80	Chairman
Andrew Sinclair (1)(3)	47	Director
William G. Harris(1)(2)	59	Director
Mahendra Shah(2)(3)	72	Director
Stuart Collinson(1)(3)	58	Director

(1) Member of the audit committee.
(2) Member of the compensation committee.
(3) Member of the nominating and corporate governance committee.

Executive Officers

Anish Bhatnagar, M.D. Dr. Bhatnagar was appointed as our Chief Executive Officer in February 2014. Prior to that, he served as our President and Chief Operating Officer. Dr. Bhatnagar joined us in 2006, and has held positions of increasing responsibility since then. Dr. Bhatnagar is a physician with over 15 years of experience in the medical device and biopharmaceutical industries. His experience spans development of biologics, drugs, drug-device combinations and diagnostic as well as therapeutic medical devices. His prior experience includes working at Coulter Pharmaceuticals, Inc. from 1998 to 2000 and Titan Pharmaceuticals, Inc. from 2000 to 2006. He is the author of several peer-reviewed publications, abstracts and book chapters. He obtained his medical degree at SMS Medical College in Jaipur, India and completed his Residency and Fellowship training in the U.S. at various institutions, including Georgetown University Hospital and the University of Pennsylvania.

We believe Dr. Bhatnagar is able to make valuable contributions to our board of directors due to his service as an executive officer of our company, including as Chief Executive Officer, extensive knowledge of medical device and pharmaceutical company operations, and extensive experience working with companies, regulators and other stakeholders in the medical device and pharmaceutical industries.

Jonathan Wolter. Mr. Wolter was appointed as our Chief Financial Officer in May 2018 after being retained as our interim Chief Financial Officer. He is a partner of FLG Partners, a leading Silicon Valley chief financial officer services and board advisory consultancy. He has over 40 years of financial and operational experience and has been a partner at FLG Partners since August 2004, during which time he has served as chief financial officer and advisor for multiple life sciences companies. Prior to joining FLG, Mr. Wolter served as Chief Financial Officer of KPMG Consulting, Latin America, and International Controller with KPMG Consulting, and has held senior financial management positions with several publicly-traded companies, including Exponent and First Republic Bancorp.

We believe Mr. Wolter is able to make valuable contributions as a chief financial officer of our company as a result of his prior financial experience in related industries that are applicable to us.

Kristen Yen, MS. Ms. Yen has over 15 years of clinical research experience in the pharmaceutical and medical device industries. She joined the Company 2006, and currently serves as the head of Clinical Operations. Prior to joining the Company, she managed multiple U.S. and global clinical studies in oncology, and held various positions of increasing responsibility at Titan Pharmaceuticals. She began her career in the industry as a clinical employee at PRA International. She has served as a team member and managed clinical studies in neonatology, neurology, pulmonary/allergy, cardiovascular disease, endocrine/metabolic disease, and oncology. She earned a Bachelor of Science degree in mathematics from the University of California, Davis, and a Master of Science degree in cell, molecular and neurosciences from the University of Hawaii, Manoa.

We believe Ms. Yen is able to make valuable contributions as an executive officer of our company as a result of her prior technical experience in our industry and related industries.

Non-Employee Directors

Ernest Mario, Ph. D. Dr. Mario joined our Board of Directors in August 2007 and served as Chairman and Chief Executive Officer until February 2014 when he was named Chairman. From April 2003 to August 2007, Dr. Mario served as Chief Executive Officer and Chairman of Reliant Pharmaceuticals, Inc., a privately held pharmaceutical company that was acquired by GSK for approximately $1.6 billion in 2007. Dr. Mario served as Chief Executive Officer and Chairman of ALZA Corporation, a research-based pharmaceutical company, from November 1997 to December 2001, when ALZA was acquired by Johnson & Johnson for approximately $12 billion. Previously he served as Chief Executive Officer and Co-Chairman of ALZA from August 1993 to November 1997. From January 1992 until March 1993, Dr. Mario served as Deputy Chairman of Glaxo Holdings plc., a pharmaceutical company, and as Chief Executive from May 1989 to March 1993. Dr. Mario has current and past service on a number of corporate boards including Boston Scientific Corporation, Celgene Inc. (current), Chimerix, Inc. (current), Kindred Biosciences Inc., Tonix Pharmaceuticals Holding Corp. (current) and XenoPort Inc. Dr. Mario earned his M.S. and Ph.D. in physical sciences at the University of Rhode Island and a B.S. in pharmacy at Rutgers. He holds honorary doctorates from the University of Rhode Island and Rutgers University. In 2007, he was awarded the Remington Medal by the American Pharmacists' Association, pharmacy's highest honor.

We believe Dr. Mario is able to make valuable contributions to our board of directors due to his extensive knowledge of our company, the industry, and our competitors, his extensive experience in risk oversight, quality and business strategy as a result of serving in leadership roles at multiple companies, his status as a significant stockholder and his prior service as our Chief Executive Officer.

Andrew Sinclair, PhD. Dr. Sinclair has been a member of our Board of Directors since December 2018. Since 2008, Dr. Sinclair has held various positions at Abingworth LLP, a life sciences investment group, where he is currently a Partner and Portfolio Manager. Dr. Sinclair is a member of the Institute of Chartered Accountants in England and Wales and received a Ph.D. in chemistry and genetic engineering at the BBSRC Institute of Plant Science, Norwich, and a B.Sc. in microbiology from King's College London.

We believe Dr. Sinclair is able to make valuable contributions to our board of directors due to his education and significant experience in the biotechnology and pharmaceutical industries.

William G. Harris. Mr. Harris has been a member of our board of directors since June 2014. Since 2001, he has been the Senior Vice President of Finance and Chief Financial Officer of Xenoport, Inc. From 1996 to 2001, he held several positions with Coulter Pharmaceutical, Inc., a biotechnology company engaged in the development of novel therapies for the treatment of cancer and autoimmune diseases, the most recent of which was Senior Vice President and Chief Financial Officer, Corixa Corp., a developer of immunotherapeutic products, which was acquired by Coulter Pharmaceutical in 2000. Prior to Coulter Pharmaceutical, from 1990 to 1996, Mr. Harris held several positions at Gilead Sciences, Inc., the most recent of which was director of finance. Mr. Harris received a B.A. from the University of California, San Diego and an M.B.A. from Santa Clara University, Leavey School of Business and Administration.

We believe Mr. Harris is able to make valuable contributions to our board of directors due to his vast experience as a finance professional in the biomedical and pharmaceutical industries.

Mahendra G. Shah, Ph.D. Dr. Shah has been a member of our board of directors since March 2017. Dr. Shah has been with at Vivo Capital, LLC, a healthcare focused investment firm, since March 2010, and is currently serving as its managing director. Dr. Shah is the founder and executive chairman of Semnur Pharmaceuticals. Dr. Shah previously served as chairman of the board of Essentialis, as a board member of Bolt Therapeutics, Impel Neuropharma, Fortis Inc., Crinetic Pharmaceuticals, Verona Pharma and a member of the board of trustees of St. John's University. He is also a board member and charter member of EPPIC and a charter member of TIE. From September 2005 to December 2009, he was the founder, chairman and CEO of NextWave Pharmaceuticals, a pediatric focused specialty pharmaceutical company, which was acquired by Pfizer. From 1993 to May 2003, he was the chairman and CEO of First Horizon Pharmaceuticals, a publicly traded specialty pharmaceutical company before it was sold to Shionogi Pharmaceuticals. From 1991 to October 1999, he was vice president of E. J. Financial Enterprises, Inc., a healthcare fund management company. He previously served on the boards of Biotie therapies (BITI), Unimed Pharmaceuticals (UMED), Introgen Therapeutics (INGN), Inpharmakon, Protomed, Structural Bioinformatics, and Zarix. From 1987 to 1991 he was the senior director of new business development with Fujisawa USA (Astellas). Prior to that time he worked in various scientific and management positions with Schering-Plough and Bristol Myers-Squibb. Dr. Shah received his Ph.D. in industrial pharmacy from St. John's University and his Bachelor's and Master's Degree in Pharmacy from L.M. College of Pharmacy in Gujarat, India.

We believe Dr. Shah is able to make a valuable contribution to our Board of Directors due to his vast experience as a finance professional in the biomedical and pharmaceutical industries.

Stuart J.M Collinson, Ph.D. Dr. Collinson has been a member of our board of directors since March 2017. He currently serves as a partner at Forward Ventures, a venture capital firm. Previously he was Chairman and CEO of Aurora Biosciences. Dr. Collinson is currently the Chief Executive Officer and member of the board of Tioga Pharmaceuticals from 2005 and Arcturus Therapeutics from 2014. He was a member of the boards of Affinium Pharmaceuticals from 2007 to 2014, Oxagen from 2001 to 2012 and VertexPharmaceuticals from 2002 to 2011. Dr. Collinson held senior management positions with Glaxo Wellcome from December 1994 to June 1998, most recently serving as Co-Chairman, Hospital and Critical Care Therapy Management Team and Director of Hospital and Critical Care. Dr. Collinson received his Ph.D. in physical chemistry from the University of Oxford, England and his M.B.A. from Harvard University.

We believe Dr. Collinson is able to make valuable contributions to our Board of Directors due to his significant financial experience and his expertise in our industry.

Board Composition

Our business and affairs are managed under the direction of our board of directors, which currently consists of six members. The members of our board of directors were elected in compliance with the provisions of our amended and restated certificate of incorporation. None of our stockholders have any special rights regarding the election or designation of members of our board of directors.

In accordance with our amended and restated certificate of incorporation, our board of directors is divided into three classes with staggered three-year terms. At each annual general meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors are divided among the three classes as follows:

- Class III currently has no directors;
- The Class II directors are Drs. Bhatnagar, Collinson and Mario and Mr. Harris, and their terms will expire at our annual meeting of stockholders to be held in 2020; and
- The Class I directors are Drs. Sinclair and Shah, and their terms will expire at our annual meeting of stockholders to be held in 2021.

We expect that additional directorships resulting from an increase in the number of directors will be assigned to Class III so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms could potentially delay or prevent a change of our management or a change in control of our company.

Director Independence

Under the listing requirements and rules of The NASDAQ Capital Market, or NASDAQ, independent directors must comprise a majority of a listed company’s board of directors.

Our board of directors performed a review of its composition, the composition of its committees, and the independence of each director. Based upon information requested from and provided by each director concerning such director’s background, employment and affiliations, including family relationships, our board of directors determined that Mr. Harris, and Drs. Sinclair, Shah and Collinson have no relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is “independent,” as that term is defined under the applicable rules and regulations of the SEC, and the listing requirements and rules of NASDAQ. In making this determination, our board of directors considered the current and prior relationships that each non-employee director has with our company, any other transactional relationships a non-employee director may have with our company, and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock held by each non-employee director and any of his and our respective affiliates.

Board Leadership Structure

Our board of directors has a Chairman, Dr. Mario, who has authority, among other things, to preside over board of directors meetings, and to call special meetings of the board of directors. Accordingly, the Chairman has substantial ability to shape the work of our board of directors. We currently believe that separation of the roles of Chairman and Chief Executive Officer reinforces the leadership role of our board of directors in its oversight of the business and affairs of our company. In addition, we currently believe that having a separate Chairman creates an environment that is more conducive to objective evaluation and oversight of management's performance, increasing management accountability and improving the ability of our board of directors to monitor whether management's actions are in the best interests of our company and its stockholders. However, no single leadership model is right for all companies and at all times. Our board of directors recognizes that depending on the circumstances, other leadership models, such as combining the role of Chairman with the role of Chief Executive Officer, might be appropriate. As a result, our board of directors may periodically review its leadership structure.

Board Committees

Our board of directors has the authority to appoint committees to perform certain management and administration functions. Our board of directors has an audit committee, a compensation committee and a nominating and corporate governance committee. The composition and responsibilities of each committee are described below. Members will serve on these committees until their resignation or until otherwise determined by our board of directors. The inclusion of our website address in this prospectus does not incorporate by reference the information on or accessible through our website into this prospectus.

Audit committee

Our audit committee consists of Andrew Sinclair, Stuart Collinson and William G. Harris, each of whom satisfies the independence requirements under NASDAQ listing standards and Rule 10A-3(b)(1) of the Exchange Act. The chairperson of our audit committee is Mr. Harris. Each member of our audit committee can read and understand fundamental financial statements in accordance with audit committee requirements. In arriving at this determination, our board of directors has examined each audit committee member's scope of experience and the nature of their employment in the corporate finance sector.

Our audit committee oversees our corporate accounting and financial reporting process and assists our board of directors in oversight of the integrity of our financial statements, our compliance with legal and regulatory requirements, our independent auditor's qualifications, independence and performance and our internal accounting and financial controls. Our audit committee is responsible for the appointment, compensation, retention and oversight of our independent auditors. Our board of directors has determined that Mr. Harris is an audit committee financial expert, as defined by the rules promulgated by the Securities Exchange and Commission.

The charter of the audit committee is available on our website at *www.soleno.life*. The inclusion of our website address in this prospectus does not include or incorporate by reference into this prospectus the information on or accessible through our website.

Compensation committee

Our compensation committee consists of William G. Harris, Mahendra Shah and Ernest Mario, each of whom our board of directors has determined to be independent under NASDAQ listing standards, a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act, and an "outside director" as that term is defined in Section 162(m) of the Code. The chairperson of our compensation committee is Dr. Shah.

Our compensation committee oversees our compensation policies, plans and benefits programs and assists our board of directors in meeting its responsibilities with regard to oversight and determination of executive compensation. In addition, our compensation committee reviews and makes recommendations to our board of directors with respect to our major compensation plans, policies and programs and assesses whether our compensation structure establishes appropriate incentives for officers and employees.

The charter of the compensation committee is available on our website at *www.soleno.life*. The inclusion of our website address in this prospectus does not include or incorporate by reference into this prospectus the information on or accessible through our website.

Nominating and corporate governance committee

Our nominating and corporate governance committee consists of Andrew Sinclair, Mahendra Shah and Stuart Collinson, each of whom our board of directors has determined to be independent under NASDAQ listing standards. The chairperson of our nominating and corporate governance committee is Dr. Sinclair.

Our nominating and corporate governance committee is responsible for making recommendations to our board of directors regarding candidates for directorships and the size and composition of the board of directors and its committees. In addition, our nominating and corporate governance committee is responsible for reviewing and making recommendations to our board of directors on matters concerning corporate governance and conflicts of interest.

The charter of the nominating and corporate governance committee is available on our website at *www.soleno.life*. The inclusion of our website address in this prospectus does not include or incorporate by reference into this prospectus the information on or accessible through our website.

Role in Risk Oversight

Our board of directors oversees an enterprise-wide approach to risk management, designed to support the achievement of business objectives, including organizational and strategic objectives, to improve long-term organizational performance and enhance stockholder value. The involvement of our board of directors in setting our business strategy is a key part of its assessment of management's plans for risk management and its determination of what constitutes an appropriate level of risk for our company. The participation of our board of directors in our risk oversight process includes receiving regular reports from members of senior management on areas of material risk to our company, including operational, financial, legal and regulatory, and strategic and reputational risks.

While our board of directors has the ultimate responsibility for the risk management process, senior management and various committees of our board of directors also have responsibility for certain areas of risk management.

Our senior management team is responsible for day-to-day risk management and regularly reports on risks to our full board of directors or a relevant committee. Our finance and regulatory personnel serve as the primary monitoring and evaluation function for company-wide policies and procedures, and manage the day-to-day oversight of the risk management strategy for our ongoing business. This oversight includes identifying, evaluating, and addressing potential risks that may exist at the enterprise, strategic, financial, operational, compliance and reporting levels.

Our audit committee focuses on monitoring and discussing our major financial risk exposures and the steps management has taken to monitor and control such exposures, including our risk assessment and risk management policies. As appropriate, the audit committee provides reports to and receive direction from the full board of directors regarding our risk management policies and guidelines, as well as the audit committee's risk oversight activities.

In addition, our compensation committee assesses our compensation policies to confirm that the compensation policies and practices do not encourage unnecessary risk taking. The compensation committee reviews and discusses the relationship between risk management policies and practices, corporate strategy and senior executive compensation and, when appropriate, report on the findings from the discussions to our board of directors. Our compensation committee intends to set performance metrics that will create incentives for our senior executives that encourage an appropriate level of risk-taking that is commensurate with our short-term and long-term strategies.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. The code of business conduct and ethics is available on our website at *www.soleno.life*. We intend to disclose any amendments to the code, or any waivers of its requirements, on our website to the extent required by the applicable rules and exchange requirements. The inclusion of our website address in this prospectus does not incorporate by reference the information on or accessible through our website into this prospectus.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has ever been an officer or employee of our company. None of our executive officers serve, or have served during the last fiscal year, as a member of a board of directors, compensation committee or other board committee performing equivalent functions of any entity that has one or more executive officers serving on our board directors or on our compensation committee.

Non-Employee Director Compensation

Directors who are employees do not receive any additional compensation for their service on our board of directors. We reimburse our non-employee directors for their reasonable out-of-pocket costs and travel expenses in connection with their attendance at board of directors and committee meetings.

Except as noted below, the following table sets forth information regarding compensation earned by our non-employee directors during the fiscal year ended December 31, 2018.

Name	Cash Compensation	Option Awards(1)	Stock Awards(2)	Total
Ernie Mario(3)	$ —	$ 20,084	$ 63,750	$ 83,834
William G. Harris(4)	$ 17,380	$ 20,084	$ 38,473	$ 75,937
Rajen Dalal(5)	$ 13,351	$ 20,084	$ 29,917	$ 63,352
James Glasheen (6)	$ 13,918	$ 20,084	$ 33,733	$ 67,735
Stuart Collinson (7)	$ —	$ 20,084	$ 40,827	$ 60,911
Mahendra Shah (8)	$ 14,260	$ 20,084	$ 36,467	$ 70,811
Andrew Sinclair (9)	$ —	$ 20,231	$ —	$ 20,231

(1) The amounts in this column reflect the aggregate grant date fair value of each option award granted during the fiscal year, computed in accordance with FASB ASC Topic 718. The valuation assumptions used in determining such amounts are described in Note 10 to our financial statements included in this prospectus. The table below lists the aggregate number of shares and additional information with respect to the outstanding option awards held by each of our non-employee directors.

(2) The amounts in this column reflect the aggregate grant date fair value of the common shares issued to board members in lieu of cash payments for quarterly board fees. Payment in shares of the Company’s common stock is made after the close of the quarter in which the compensation is earned. The grant date fair value for common shares is determined using the closing price of our common stock on the issuance date.

(3) Dr. Mario joined our Board in August 2007. During 2018, Dr. Mario was granted an option to purchase 15,931 shares of our common stock, of which 100% of the shares vest on the earlier of the 12 month anniversary of the date of grant or the day before the next annual meeting of stockholders, subject to continued service through each such date. Dr. Mario was also issued 33,354 shares of common stock in lieu of cash payments for quarterly board fees, paid quarterly in the quarter following when the compensation is earned.

(4) Mr. Harris joined our Board in June 2014. During 2018, Mr. Harris was granted an option to purchase 15,931 shares of our common stock, of which 100% of the shares vest on the earlier of the 12 month anniversary of the date of grant or the day before the next annual meeting of stockholders, subject to continued service through each such date. Mr. Harris was also issued 20,205 shares of common stock in lieu of cash payments for quarterly board fees, paid quarterly in the quarter following when the compensation is earned.

(5) Mr. Dalal joined our Board in April 2016. During 2018, Mr. Dalal was granted an option to purchase 15,931 shares of our common stock, of which 100% of the shares vest on the earlier of the 12 month anniversary of the date of grant or the day before the next annual meeting of stockholders, subject to continued service through each such date. Mr. Dalal was also issued 15,739 shares of common stock in lieu of cash payments for quarterly board fees, paid quarterly in the quarter following when the compensation is earned. Mr. Dalal resigned from our Board effective January 1, 2019.

(6) Dr. Glasheen joined our Board in March 2017. During 2018, Dr. Glasheen was granted an option to purchase 15,931 shares of our common stock, of which 100% of the shares vest on the earlier of the 12 month anniversary of the date of grant or the day before the next annual meeting of stockholders, subject to continued service through each such date. Dr. Glasheen was also issued 17,777 shares of common stock in lieu of cash payments for quarterly board fees, paid quarterly in the quarter following when the compensation is earned. Dr. Glasheen resigned from our Board effective October 16, 2018.

(7) Dr. Collinson joined our Board in March 2017. During 2018, Dr. Collinson was granted an option to purchase 15,931 shares of our common stock, of which 100% of the shares vest on the earlier of the 12 month anniversary of the date of grant or the day before the next annual meeting of stockholders, subject to continued service through each such date. We also issued 21,168 shares of common stock to Forward Ventures, of whom Dr. Collinson is a general partner, in lieu of cash payments for quarterly board service fees, paid quarterly in the quarter following when the compensation is earned.

(8) Dr. Shah joined our Board in March 2017. During 2018, Dr. Shah was granted an option to purchase 15,931 shares of our common stock, of which 100% of the shares vest on the earlier of the 12 month anniversary of the date of grant or the day before the next annual meeting of stockholders, subject to continued service through each such date. Dr. Shah was also issued 19,562 shares of common stock in lieu of cash payments for quarterly board fees, paid quarterly in the quarter following when the compensation is earned.

(9) Dr. Sinclair joined our Board in December 2018. During 2018, Dr. Sinclair was granted an option to purchase 20,000 shares which vests as to 1/48th of the shares each month, subject to continued service through each such date.

Our board of directors has adopted a non-employee director compensation policy pursuant to which we will compensate our non-employee directors with a combination of cash and equity. Each such director will receive an annual base cash retainer of $35,000 for such service, to be paid quarterly in the form of shares of our common stock. Each non-employee director will receive an annual stock option grant to purchase that number of shares representing, as of the date of grant, $32,500 of value, which shall be granted effective as of the date of each annual stockholder meeting, and share vest as to 100% of the shares on the earlier of the 12 month anniversary of the date of grant or the day before the next annual stockholder meeting. New members elected to the board of directors shall receive a stock option grant to purchase 20,000 shares of common stock, which shall vest monthly over four years. The policy also provides that we compensate certain members of our Board of Directors for service on our committees as follows:

- The chair or executive chair of our board of directors will receive an annual cash retainer of $25,000 for such service, paid quarterly;
- The chairperson of our audit committee will receive an annual cash retainer of $15,000 for such service and each other member of the audit committee will receive an annual cash retainer of $7,500 for such service, paid quarterly;
- The chairperson of our compensation committee will receive an annual cash retainer of $10,000 for such service and each other member of the compensation committee will receive an annual cash retainer of $5,000 for such service, paid quarterly; and
- The chairperson of our nominating and corporate governance committee will receive an annual cash retainer of $7,000 for such service and each other member of the nominating and corporate governance committee will receive an annual cash retainer of $3,500, paid quarterly.

EXECUTIVE COMPENSATION

As an emerging growth company, we have opted to comply with the executive compensation disclosure rules applicable to “smaller reporting companies,” as such term is defined in the rules promulgated under the Securities Act, which require compensation disclosure for our principal executive officer and the two most highly compensated executive officers other than our principal executive officer. Our named executive officers for the year ended December 31, 2018 are:

- Anish Bhatnagar, M.D., our Chief Executive Officer, President and Chief Operating Officer;
- Jonathan Wolter, our Chief Financial Officer; and
- Kristen Yen, our Vice President, Clinical Operations.

Throughout this section, we refer to these three officers as our named executive officers.

2018 Summary Compensation Table

The Summary Compensation Table below sets forth information regarding the compensation awarded to or earned by our named executive officers during the years ended December 31, 2018 and 2017.

Summary Compensation Table

Name and Position	Year Ended December 31,	Salary	Bonus(1)	Stock Awards(2)	Option Awards(3)	Non-equity Incentive Plan Compensation	Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Anish Bhatnagar	2018	$ 460,000	$ 80,500	—	$ 411,411	—	—	—	$ 951,911
Chief Executive Officer, President and Chief Operating Officer	2017	$ 460,000	$ 84,367	$ 76,633	$ 612,455	—	—	—	$ 1,233,455
Jonathan Wolter (4) Chief Financial Officer	2018	$ 243,000	—	—	$ 45,000	—	—	—	$ 288,000
Kristen Yen (5) Vice President, Clinical Operations	2018	$ 235,000	$ 20,560	—	$ 77,139	—	—	—	$ 332,699

(1) Bonus awards for executives are accrued ratably throughout the year and are subject to review and approval by the Compensation Committee of the Board of Directors subsequent to the year in which they are earned and accrued.

(2) The amounts in this column represent the aggregate grant date fair value of restricted stock unit awards (RSUs) earned during the years ended December 31, 2018, 2017 and 2016, as applicable, computed in accordance with FASB ASC Topic 718. The grant date fair value for the RSUs is estimated using the closing price of our common stock on the date of grant.

(3) The amounts in this column reflect the aggregate grant date fair value of each option award granted during the fiscal years ended December 31, 2018, 2017 and 2016, as applicable, computed in accordance with FASB ASC Topic 718. The valuation assumptions used in determining such amounts are described in the Notes to our audited financial statements for the year ended December 31, 2018, 2017 and 2016.

(4) Mr. Wolter became a named executive officer during 2018 and therefore compensation for earlier years is not provided. Mr. Wolter is a part-time consultant to the Company whose fees earned during 2018 are reported as Salary.

(5) Ms. Yen became a named executive officer during 2018 and therefore compensation for earlier years is not provided.

Employment Agreements

We have entered into agreements with our named executive officers. The agreements provides for “at-will” employment and set forth the terms and conditions of employment, including annual base salary, target bonus opportunity, equity compensation, severance benefits and eligibility to participate in our employee benefit plans and programs. In connection with their employment, Anish Bhatnagar and Kristen Yen were also required to execute our standard employment, confidential information, invention assignment and arbitration agreement. As an independent contractor, Jonathan Wolter’s relationship with the Company is subject to the terms of the Confidential Consulting Agreement described below. The material terms of these employment agreements are summarized below.

These summaries are qualified in their entirety by reference to the actual text of the agreements, which are attached as exhibits to this registration statement.

Agreement with Anish Bhatnagar

We entered into an employment agreement with Dr. Bhatnagar, dated May 15, 2015, pursuant to which Dr. Bhatnagar serves as our President and Chief Executive Officer. The agreement provides for "at-will" employment and sets forth certain agreed upon terms and conditions of employment. Dr. Bhatnagar's current annual base salary is $460,000 and he has an annual target bonus equal to 25% of his base salary.

Potential payments and benefits upon termination or change of control

Dr. Bhatnagar. Pursuant to Dr. Bhatnagar's employment agreement, if Dr. Bhatnagar's employment is terminated without "Cause" (as defined in Dr. Bhatnagar's employment agreement) or resignation by the employee for "Good Reason" (as defined in Dr. Bhatnagar's employment agreement), and subject to Dr. Bhatnagar signing and not revoking a separation agreement and release of claims, then Dr. Bhatnagar will be entitled to the following severance payments and benefits:

- If Dr. Bhatnagar's termination or resignation occurs prior to six (6) months before a Change in Control (as defined in Dr. Bhatnagar's employment agreement) of the Company: (i) continuing payments of severance pay at a rate equal to Dr. Bhatnagar's base salary rate for fifteen (15) months from the date of such termination without Cause or resignation for Good Reason; (ii) if Dr. Bhatnagar elects continuation coverage pursuant to the Consolidated Budget Reconciliation Act of 1985 ("COBRA"), then the Company will reimburse Dr. Bhatnagar on the last day of each month for a period ending fifteen (15) months after Dr. Bhatnagar's termination date for the COBRA premiums paid during such period for such coverage (at the coverage levels in effect immediately prior to Dr. Bhatnagar's termination); and (iii) twenty-five percent (25%) of any unvested equity awards held by Dr. Bhatnagar as of the date of such termination without Cause or resignation for Good Reason shall immediately vest and become fully exercisable;
- If such termination or resignation occurs within six (6) months prior to, or twelve (12) months following, a Change in Control of the Company: (i) continuing payments of severance pay at a rate equal to Dr. Bhatnagar's base salary rate for eighteen (18) months from the date of such termination without Cause or resignation for Good Reason; (ii) if Dr. Bhatnagar elects continuation coverage pursuant to COBRA, then the Company will reimburse Dr. Bhatnagar on the last day of each month for a period ending eighteen (18) months after Dr. Bhatnagar's termination date for the COBRA premiums paid during such period for such coverage (at the coverage levels in effect immediately prior to Dr. Bhatnagar's termination); (iii) a payment equal to one hundred fifty percent (150%) the annual target bonus opportunity for the year in which Dr. Bhatnagar is terminated without Cause or resigns for Good Reason; and (iv) one hundred percent (100%) of any unvested equity awards held by Dr. Bhatnagar as of the date of such termination without Cause or resignation for Good Reason shall immediately vest and become fully exercisable; and
- If Dr. Bhatnagar is terminated without Cause or resigns for Good Reason during the term of Dr. Bhatnagar's employment agreement, then Dr. Bhatnagar's shall have one year following such termination without Cause or resignation for Good Reason to exercise any then vested options.

Agreement with Jonathan Wolter

We entered into a Confidential Consulting Agreement with FLG Partners, LLC, dated September 5, 2017, pursuant to which Mr. Wolter, a partner of FLG Partners, LLC, serves as our Chief Financial Officer. The agreement provides hourly services as the Company's Chief Financial Officer at a rate of $375 per hour. Either party may terminate the Confidential Consulting Agreement upon thirty days notice.

Agreement with Kristen Yen

We entered into an employment agreement with Ms. Yen, dated May 15, 2015, pursuant to which Ms. Yen serves as our Vice President, Clinical & Regulatory Affairs. The agreement provides for "at-will" employment and sets forth certain agreed upon terms and conditions of employment. Ms. Yen's current annual base salary is $250,000 and she has an annual target bonus equal to 25% of her base salary.

Potential payments and benefits upon termination or change of control

Ms. Yen. Pursuant to Ms. Yen's employment agreement, if Ms. Yen's employment is terminated without "Cause" (as defined in Ms. Yen's employment agreement) or resignation by the employee for "Good Reason" (as defined in Ms. Yen's employment agreement), and subject to Ms. Yen signing and not revoking a separation agreement and release of claims, then Ms. Yen will be entitled to the following severance payments and benefits:

- If Ms. Yen's termination or resignation occurs prior to three (3) months before a Change in Control (as defined in Ms. Yen's employment agreement) of the Company: (i) continuing payments of severance pay at a rate equal to Ms. Yen's base salary rate for six (6) months from the date of such termination without Cause or resignation for Good Reason; (ii) if Ms. Yen elects continuation coverage pursuant to the Consolidated Budget Reconciliation Act of 1985 ("COBRA"), then the Company will reimburse Ms. Yen on the last day of each month for a period ending three (3) months after Ms. Yen's termination date for the COBRA premiums paid during such period for such coverage (at the coverage levels in effect immediately prior to Ms. Yen's termination);
- If such termination or resignation occurs within three (3) months prior to, or six (6) months following, a Change in Control of the Company: (i) continuing payments of severance pay at a rate equal to Ms. Yen's base salary rate for twelve (12) months from the date of such termination without Cause or resignation for Good Reason; (ii) if Ms. Yen elects continuation coverage pursuant to COBRA, then the Company will reimburse Ms. Yen on the last day of each month for a period ending six (6) months after Ms. Yen's termination date for the COBRA premiums paid during such period for such coverage (at the coverage levels in effect immediately prior to Ms. Yen's termination); (iii) a payment equal to fifty percent (50%) the annual target bonus opportunity for the year in which Ms. Yen is terminated without Cause or resigns for Good Reason; and (iv) one hundred percent (100%) of any unvested equity awards held by Ms. Yen as of the date of such termination without Cause or resignation for Good Reason shall immediately vest and become fully exercisable.

Outstanding Equity Awards at December 31, 2018

The following table provides information regarding outstanding equity awards held by our named executive officers as of December 31, 2018.

		Number of Securities Underlying Unexercised Options			
Name	**Grant Date**	**Exercisable**	**Unexercisable**	**Option Exercise Price**	**Option Expiration Date**
Anish Bhatnagar					
	11/12/2014	86,050(1)	—	$ 35.70	11/12/2024
	1/11/2015	42,578(2)	447	$ 9.00	1/11/2025
	5/15/2015	27,658(4)	2,342	$ 23.30	5/15/2025
	1/10/2016	43,750(3)	16,250	$ 8.05	1/10/2026
	6/8/2016	48,940(2)	11,295	$ 6.00	6/8/2026
	4/19/2017	192,075(4)	144,714	$ 2.95	4/19/2027
	2/7/2018	83,334(3)	316,666	$ 1.60	2/7/2028
Jonathan Wolter					
	6/15/2018	12,000(5)	12,000	$ 2.33	6/15/2028
Kristen Yen					
	6/3/2010	833(1)	—	$ 6.00	6/3/2020
	11/12/2014	10,478(1)	—	$ 35.70	11/12/2024
	1/11/2015	1,955(4)	45	$ 9.00	1/11/2025
	1/11/2015	2,582(4)	38	$ 9.00	1/11/2025
	1/10/2016	7,294(3)	2,706	$ 8.05	1/10/2026
	6/8/2016	5,272(4)	2,063	$ 6.00	6/8/2026
	4/19/2017	14,901(4)	11,226	$ 2.95	4/19/2027
	2/7/2018	15,626(3)	59,374	$ 1.60	2/7/2028

(1) The options listed are fully vested and may be exercised in full.
(2) The shares subject to the stock option vest over a four-year period as follows: 50% of the shares vest immediately on the vesting commencement date, and thereafter 1/48th of the remaining shares vest each month, subject to the officer's continued service to us through each vesting date.
(3) The shares subject to the stock option vest over a four-year period as follows: 1/48th of the shares vest each month beginning on the vesting commencement date, subject to the officer's continued service to us through each vesting date.

(4) The shares subject to the stock option vest over a four-year period as follows: 25% of the shares underlying the option vest immediately on the vesting commencement date and thereafter 1/48th of the remaining shares vest each month, subject to the officer's continued service to us through each vesting date.

(5) The shares subject to the stock option vest over a one-year period as follows: 25% of the shares vest each quarter beginning on the vesting commencement date, subject to the officer's continued service to us through each vesting date.

Securities Authorized for Issuance under Equity Compensation Plans

2014 Equity Incentive Plan

We have adopted the 2014 Equity Incentive Plan, or the 2014 Plan. Our 2014 Plan provides for the grant of incentive stock options (within the meaning of Section 422 of the Code), or ISOs, to our employees and any of our parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, or NSOs, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to our employees, directors and consultants, and our parent and subsidiary corporations' employees and consultants.

Plan Administration. Subject to the provisions of our 2014 Plan, the administrator has the power to determine the terms of the awards, including the exercise price, the number of shares subject to each such award, the exercisability of the awards, and the form of consideration, if any, payable upon exercise. The administrator also has the authority to amend existing awards to reduce their exercise price, to allow participants the opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator and to institute an exchange program by which outstanding awards may be surrendered in exchange for awards with a higher or lower exercise price.

Stock Options. The exercise price of options granted under our 2014 Plan must at least be equal to the fair market value of our common stock on the date of grant. The term of an incentive stock option may not exceed ten years, except that with respect to any participant who owns more than 10% of the voting power of all classes of our outstanding stock, the term must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date. Subject to the provisions of our 2014 Plan, the administrator will determine the term of all other options.

After the termination of service of an employee, director or consultant, he or she may exercise his or her option or stock appreciation right for the period of time stated in his or her award agreement. Generally, if termination is due to death or disability, the option or stock appreciation right will remain exercisable for twelve months. In all other cases, the option or stock appreciation right will generally remain exercisable for three months following the termination of service. However, in no event may an option be exercised later than the expiration of its term.

Stock Appreciation Rights. Stock appreciation rights may be granted under our 2014 Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our common stock between the exercise date and the date of grant. Subject to the provisions of our 2014 Plan, the administrator determines the terms of stock appreciation rights, including when such rights become exercisable and whether to pay any increased appreciation in cash or with shares of our common stock, or a combination thereof, except that the per share exercise price for the shares to be issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share on the date of grant.

Restricted Stock. Restricted stock may be granted under our 2014 Plan. Restricted stock awards are grants of shares of our common stock that vest in accordance with terms and conditions established by the administrator. The administrator determines the number of shares of restricted stock granted and may impose whatever conditions to vesting it determines to be appropriate (for example, the administrator may set restrictions based on the achievement of specific performance goals or continued service to us). The administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. Shares of restricted stock that do not vest are subject to our right of repurchase or forfeiture.

Restricted Stock Units. Restricted stock units may be granted under our 2014 Plan. Restricted stock units are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. The administrator will determine the terms and conditions of restricted stock units, including the number of units granted, the vesting criteria (which may include accomplishing specified performance criteria or continued service to us), and the form and timing of payment. The administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed.

Performance Units and Performance Shares. Performance units and performance shares may be granted under our 2014 Plan. Performance units and performance shares are awards that will result in a payment to a participant only if performance goals established by the administrator are achieved or the awards otherwise vest. The administrator will establish organizational or individual performance goals in its discretion, which, depending on the extent to which they are met, will determine the number or the value of performance units and performance shares to be paid out to participants. After the grant of a performance unit or performance share, the administrator, in its sole discretion, may reduce or waive any performance objectives or other vesting provisions for such performance units or performance shares. The administrator, in its sole discretion, may pay earned performance units or performance shares in the form of cash, in shares, or in some combination thereof.

Non-Employee Directors. Our 2014 Plan provides that all non-employee directors will be eligible to receive all types of awards (except for ISOs) under the 2014 Plan. Please see the description of our non-employee director compensation above under "Management — Non-Employee Director Compensation."

Non-Transferability of Awards. Unless the administrator provides otherwise, our 2014 Plan generally does not allow for the transfer of awards, and only the recipient of an award may exercise an award during his or her lifetime.

Certain Adjustments. In the event of certain changes in our capitalization, to prevent diminution or enlargement of the benefits or potential benefits available under the 2014 Plan, the administrator will adjust the number and class of shares that may be delivered under the 2014 Plan or the number, class and price of shares covered by each outstanding award, and the numerical share limits set forth in the 2014 Plan.

Merger or Change in Control. Our 2014 Plan provides that in the event of a merger or change in control, as defined in the 2014 Plan, each outstanding award will be treated as the administrator determines, including that the successor corporation or its parent or subsidiary will assume or substitute an equivalent award for each outstanding award. The administrator will not be required to treat all awards similarly. If there is no assumption or substitution of outstanding awards, the awards will fully vest, all restrictions will lapse, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and the awards will become fully exercisable.

2014 Employee Stock Purchase Plan

We have adopted the 2014 Employee Stock Purchase Plan, or the ESPP.

Plan Administration. Our compensation committee administers the ESPP, and has full and exclusive authority to interpret the terms of the plan and determine eligibility to participate, subject to the conditions of the plan as described below.

Eligibility. Generally, all of our employees are eligible to participate if they are employed by us, or any participating subsidiary, for at least 20 hours per week and more than five months in any calendar year. However, an employee may not be granted rights to purchase stock under the ESPP if such employee:

- immediately after the grant would own stock possessing 5% or more of the total combined voting power or value of all classes of our capital stock; or
- hold rights to purchase stock under all of our employee stock purchase plans that accrue at a rate that exceeds $25,000 worth of stock for each calendar year.

Offering Periods. Our ESPP is intended to qualify under Section 423 of the Code. Each offering period includes purchase periods, which will be the approximately six months commencing with one exercise date and ending with the next exercise date. The offering periods are scheduled to start on the first trading day on or after and of each year, except for the first offering period, which will commence on such future date as our board of directors may determine.

Our ESPP permits participants to purchase shares of common stock through payroll deductions of up to 15.0% of their eligible compensation. A participant may purchase a maximum of shares during a six-month period.

Exercise of Purchase Right. Amounts deducted and accumulated by the participant will be used to purchase shares of our common stock at the end of each six month purchase period. The purchase price of the shares will be 85.0% of the lower of the fair market value of our common stock on the first trading day of each offering period or on the exercise date. If the fair market value of our common stock on the exercise date is less than the fair market value on the first trading day of the offering period, participants will be withdrawn from the current offering period following their purchase of shares on the purchase date and will be automatically re-enrolled in a new offering period. Participants may end their participation at any time during an offering period and will be paid their accrued contributions that have not yet been used to purchase shares of common stock. Participation ends automatically upon termination of employment with us.

Non-Transferability. A participant may not transfer rights granted under the ESPP. If the compensation committee permits the transfer of rights, it may only be done by will, the laws of descent and distribution, or as otherwise provided under the ESPP.

Merger or Change in Control. In the event of our merger or change in control, as defined under the ESPP, a successor corporation may assume or substitute each outstanding purchase right. If the successor corporation refuses to assume or substitute for the outstanding purchase right, the offering period then in progress will be shortened, and a new exercise date will be set. The administrator will notify each participant that the exercise date has been changed and that the participant's option will be exercised automatically on the new exercise date unless prior to such date the participant has withdrawn from the offering period.

Certain Adjustments. In the event of certain changes in our capitalization, to prevent dilution or enlargement of the benefits or potential benefits available under the ESPP, the administrator will adjust the number and class of shares that may be delivered under the ESPP, the purchase price per share and the number of shares covered by each option and the numerical share limits set forth in the ESPP.

Amendment; Termination. Our ESPP will automatically terminate in 2034, unless we terminate it sooner. Our board of directors has the authority to amend, suspend, or terminate our ESPP, except that, subject to certain exceptions described in the ESPP, no such action may adversely affect any outstanding rights to purchase stock under our ESPP.

Employee benefit plans

Our named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, group life, and accidental death and dismemberment insurance plans, in each case, on the same basis as all of our other employees. We maintain a 401(k) plan for the benefit of our eligible employees, including our named executive officers, as discussed in the section below entitled "Employee benefit plans — 401(k) Plan."

1999 Stock Plan

Our board of directors and stockholders adopted our 1999 Incentive Stock Plan, or the 1999 Plan, in October 1999. Our 1999 Plan provided for the grant of nonstatutory stock options, or NSOs, and stock purchase rights to employees and consultants of ours or any parent or subsidiary of ours and to our directors. Our 1999 Plan also provided for the grant of incentive stock options, or ISOs (within the meaning of Section 422 of the Code), to employees of ours or any parent or subsidiary of ours. Our 1999 Stock Plan expired by its terms on October 5, 2009 and, accordingly, no further grants will be made under our 1999 Stock Plan. However, any outstanding awards granted under our 1999 Plan will remain outstanding, subject to the terms of our 1999 Plan and the applicable award agreements, until such awards are exercised or otherwise terminate or expire by their terms.

Plan administration. Our board of directors, or a duly authorized committee of our board of directors, may administer our 1999 Plan. Subject to the terms of our 1999 Plan, the administrator has the authority to determine the terms of awards, including recipients, the exercise or purchase price of the awards (if any), the number of shares subject to awards, the vesting schedule applicable to the awards, and any transfer restrictions or rights of repurchase. Additionally, the administrator has the authority to determine the fair market value of our common stock, to determine whether and under what circumstances an option may be settled in cash instead of common stock, to reduce the exercise price of an option to the then-current fair market value of our common stock, to initiate an option exchange program whereby outstanding options are exchanged for options with a lower exercise price, and to allow optionees to satisfy withholding tax obligations by electing to have us withhold otherwise deliverable shares. The administrator also has the authority to prescribe, amend, and rescind rules and regulations relating to the 1999 Plan and to construe and interpret the terms of the 1999 Plan and awards granted pursuant to the 1999 Plan. All decisions, interpretations and other actions of our board of directors will be final and binding.

Stock Options. Stock options could be granted under the 1999 Plan. The exercise price of nonstatutory stock options granted under our 1999 Plan must at least be equal to 85% of the fair market value of our common stock on the date of grant, and the exercise price of incentive stock options granted under our 1999 Plan must at least be equal to the fair market value of our common stock on the date of grant, except that with respect to any participant who owns more than 10% of the voting power of all classes of our outstanding stock, the exercise price of any option must equal to at least 110% of the fair market value on the grant date. The term of a stock option may not exceed 10 years, except that with respect to any participant who owns more than 10% of the voting power of all classes of our outstanding stock, the term of an incentive stock option must not exceed 5 years. The administrator will determine the methods of payment of the exercise price of an option, which may include cash, shares or other property acceptable to the administrator, as well as other types of consideration permitted by applicable law. After the termination of service of an employee, director or consultant, he or she may exercise his or her option for the period of time stated in his or her option agreement. Generally, if termination is due to death or disability, the option will remain exercisable for 12 months. In all other cases, the option will generally remain exercisable for three months following the termination of service. However, in no event may an option be exercised later than the expiration of its term. Subject to the provisions of our 1999 Plan, the administrator determined the other terms of options.

Stock Purchase Rights. Restricted stock could be issued pursuant to the exercise or stock purchase rights granted under our 1999 Plan. Restricted stock consists of shares of our common stock that vest in accordance with terms and conditions established by the administrator. The administrator determined the number of shares of restricted stock granted to any employee, director or consultant and, subject to the provisions of our 1999 Plan, determined the terms and conditions of such awards. The administrator could impose whatever conditions to vesting it determined to be appropriate (for example, the administrator may have set restrictions based on the achievement of specific performance goals or continued service to us); provided, however, that the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. Holders of restricted stock generally have voting and dividend rights with respect to such shares upon issuance without regard to vesting, unless the administrator provided otherwise. Shares of restricted stock that do not vest are subject to our right of repurchase or forfeiture.

Non-Transferability of Awards. Our 1999 Plan does not allow for the transfer of awards, and only the recipient of an award may exercise an award during his or her lifetime.

Certain Adjustments. In the event of certain changes in our capitalization, to prevent diminution or enlargement of the benefits or potential benefits available under the 1999 Plan, the administrator will adjust the number and class of shares that may be delivered under the 1999 Plan or the number, class and price of shares covered by each outstanding award.

Dissolution or Liquidation. In the event of our proposed dissolution or liquidation, the administrator will notify participants as soon as practicable. The administrator may allow for awards to be exercised until 15 days prior to such transaction as to all of the shares subject to such awards, including shares which would not otherwise be exercisable. In addition, the administrator may provide that any repurchase option of ours will lapse, so long as the proposed dissolution or liquidation takes place at the time and in the manner contemplated. All awards will terminate immediately prior to the consummation of such proposed transaction.

Merger or Asset Sale. Our 1999 Plan provides that in the event of a merger or sale of substantially all of the assets of our company, each outstanding award will be assumed or an equivalent award will be substituted by the successor corporation or its parent or subsidiary. If the successor corporation or its parent or subsidiary does not assume or substitute an equivalent award for any outstanding award, then such award will fully vest, and the administrator will notify the holder of the award that such award will be fully exercisable for a period of 15 days from the date of such notice. The award will then terminate upon the expiration of the specified period of time.

Plan amendment or termination. Our board of directors has the authority to amend our 1999 Plan, provided that such action does not impair the existing rights of any participant without such participant’s written consent.

2010 Stock Plan

Our board of directors and stockholders adopted our 2010 Plan in May 2010. Our 2010 Plan provided for the grant of NSOs, stock appreciation rights, restricted stock, and restricted stock units to employees and consultants of ours or any parent or subsidiary of ours and to our directors. Our 2010 Plan also provides for the grant of ISOs (within the meaning of Section 422 of the Code) to employees of ours or any parent or subsidiary of ours. Our 2010 Stock Plan was terminated in connection with our IPO, and accordingly, no further grants will be made under our 2010 Plan. However, any outstanding awards granted under our 2010 Plan will remain outstanding, subject to the terms of our 2010 Plan and the applicable award agreements, until such awards are exercised or otherwise terminate or expire by their terms.

Plan administration. Our board of directors, or a duly authorized committee of our board of directors, may administer our 2010 Plan. Subject to the terms of our 2010 Plan, the administrator will have the power to administer the 2010 Plan, including but not limited to the power to interpret the terms of the 2010 Plan and awards granted under it; to create, amend, and revoke rules relating to the 2010 Plan, including creating sub-plans; and to determine the terms of the awards, including the exercise price, the number of shares subject to each such award, the exercisability of the awards, and the form of consideration, if any, payable upon exercise. The administrator will also have the authority to amend existing awards to reduce or increase their exercise price, to allow participants the opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator, and to institute an exchange program by which outstanding awards may be surrendered in exchange for awards of the same type which may have a higher or lower exercise price or different terms, awards of a different type, or cash.

Stock Options. Stock options could be granted under the 2010 Plan. The exercise price of options granted under our 2010 Plan must at least be equal to the fair market value of our common stock on the date of grant. The term of a stock option may not exceed 10 years, except that with respect to an ISO granted to a participant who owns more than 10% of the voting power of all classes of our outstanding stock, the term must not exceed 5 years and the exercise price must equal at least 110% of the fair market value on the grant date. The administrator determined the methods of payment of the exercise price of an option, which may include cash, shares or other property acceptable to the administrator, as well as other types of consideration permitted by applicable law. After the termination of service of an employee, director or consultant, he or she may exercise his or her option for 30 days (or 6 months in the case of a termination due to death or disability) or such longer period of time stated in his or her option agreement. However, in no event may an option be exercised later than the expiration of its term. Subject to the provisions of our 2010 Plan, the administrator determines the other terms of options.

Stock Appreciation Rights. Stock appreciation rights could be granted under our 2010 Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our common stock between the exercise date and the date of grant. Stock appreciation rights may not have a term exceeding 10 years. After the termination of service of an employee, director or consultant, he or she may exercise his or her stock appreciation right for the period of time stated in his or her option agreement. However, in no event may a stock appreciation right be exercised later than the expiration of its term. Subject to the provisions of our 2010 Plan, the administrator determined the other terms of stock appreciation rights, including when such rights become exercisable and whether to pay any increased appreciation in cash or with shares of our common stock, or a combination thereof, except that the per share exercise price for the shares to be issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share on the date of grant.

Restricted Stock. Restricted stock could be granted under our 2010 Plan. Restricted stock awards are grants of shares of our common stock that vest in accordance with terms and conditions established by the administrator. The administrator determines the number of shares of restricted stock granted to any employee, director or consultant and, subject to the provisions of our 2010 Plan, determined the terms and conditions of such awards. The administrator could impose whatever conditions to vesting it determined to be appropriate (for example, the administrator may have set restrictions based on the achievement of specific performance goals or continued service to us); provided, however, that the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. Recipients of restricted stock awards generally have voting and dividend rights with respect to such shares upon grant without regard to vesting, unless the administrator provided otherwise. Shares of restricted stock that do not vest are subject to our right of repurchase or forfeiture.

Restricted Stock Units. Restricted stock units could be granted under our 2010 Plan. Restricted stock units are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. Subject to the provisions of our 2010 Plan, the administrator determined the terms and conditions of restricted stock units, including the vesting criteria (which may include accomplishing specified performance criteria or continued service to us) and the form and timing of payment. Notwithstanding the foregoing, the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed.

Non-Transferability of Awards. Unless the administrator provided otherwise, our 2010 Plan generally does not allow for the transfer of awards and only the recipient of an award may exercise an award during his or her lifetime.

Certain Adjustments. In the event of certain changes in our capitalization, to prevent diminution or enlargement of the benefits or potential benefits available under the 2010 Plan, the administrator will adjust the number and class of shares that may be delivered under the Plan or the number, class, and price of shares covered by each outstanding award, and the numerical share limits set forth in the 2010 Plan. In the event of our proposed liquidation or dissolution, the administrator will notify participants as soon as practicable and all awards will terminate immediately prior to the consummation of such proposed transaction.

Dissolution or Liquidation. In the event of our proposed dissolution or liquidation, the administrator will notify participants as soon as practicable, and all awards will terminate immediately prior to the consummation of such proposed transaction.

Change in control. Our 2010 Plan provides that in the event of a change in control, as defined under our 2010 Plan, each outstanding award will be treated as the administrator determines, except that if a successor corporation or its parent or subsidiary does not assume or substitute an equivalent award for any outstanding award, then such award will fully vest, all restrictions on such award will lapse, all performance goals or other vesting criteria applicable to such award will be deemed achieved at 100% of target levels and such award will become fully exercisable, if applicable, for a specified period prior to the transaction. The award will then terminate upon the expiration of the specified period of time.

Plan amendment or termination. Our board of directors has the authority to amend our 2010 Plan, provided that such action does not impair the existing rights of any participant without such participant’s written consent.

401(k) plan

We maintain a retirement savings plan, or 401(k) plan, that provides eligible U.S. employees with an opportunity to save for retirement on a tax advantaged basis. Under our 401(k) plan, eligible employees may defer eligible compensation subject to applicable annual contribution limits imposed by the Code. Employees' pre-tax contributions are allocated to each participant's individual account. Participants are immediately and fully vested in their contributions. We do not currently provide an employer match on employee contributions. The 401(k) plan is intended to be qualified under Section 401(a) of the Code with the 401(k) plan's related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

We describe below transactions and series of similar transactions that we were or will be a party to in which (i) an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of any class of our common stock or any member of the immediate family of any of the foregoing persons and (ii) the amount involved exceeds $120,000.

Other than as described below, there has not been, nor is there any currently proposed, transactions or series of similar transactions to which we have been or will be a party.

2018 Private Placement Common Stock Financing

On December 19, 2018, we entered into a Securities Purchase Agreement, or the Unit Purchase Agreement, with the selling stockholders pursuant to which we sold and issued 10,272,375 immediately separable units at a price per unit of $1.60625 for aggregate gross proceeds of approximately $16,500,000 Each unit consisted of one share of our common stock and a warrant to purchase 0.05 of a share of our common stock at an exercise price of $2.00 per share, for an aggregate of 10,272,375 shares of our common stock, or the Shares, and corresponding warrants, or the 2018 PIPE Warrants, to purchase 513,617 shares of our common stock, or the Warrant Shares, referred to collectively as the Resale Shares. We also granted certain registration rights to the selling stockholders pursuant to the Unit Purchase Agreement pursuant to which, among other things, we are preparing and filing this registration statement with the SEC to register for resale the Resale Shares.

Mr. Sinclair, a member of our board of directors, is an affiliate of Abingworth Bioventures VII L.P., which purchased an aggregate of 4,669,272 shares of common stock in the 2018 PIPE Offering (approximately 45.5% of the shares of common stock issued in the 2018 PIPE Offering) and warrants to purchase an aggregate of 233,463 shares of common stock (approximately 45.5% of the warrants issued in the 2018 PIPE Offering for an aggregate investment of approximately $7.5 million).

2017 Private Placement Common Stock Financing

On December 11, 2017, we entered into the Unit 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 approximately $15,000,000. Each unit consisted of one share of our common stock and a warrant to purchase 0.74 of a share of our common stock at an exercise price of $2.00 per share, for an aggregate of 8,141,116 Shares and corresponding warrants to purchase 6,024,425 Warrant Shares, together referred to as the Resale Shares. We also granted certain registration rights to the selling stockholders pursuant to the Unit Purchase Agreement pursuant to which, among other things, we filed a registration statement with the SEC to register for resale the Resale Shares in January 2018.

Dr. Shah, a member of our board of directors, is an affiliate of the entities affiliated with Vivo Ventures, which purchased an aggregate of 1,085,480 shares of common stock in the 2017 PIPE Offering (approximately 13.3% of the shares of common stock issued in the 2017 PIPE Offering) and warrants to purchase an aggregate of 803,255 shares of common stock (approximately 13.3% of the warrants issued in the 2017 PIPE Offering for an aggregate investment of approximately $2 million).

Merger with Essentialis, Inc. and Common Stock Financing

On March 7, 2017, we entered into common stock purchase agreements, or the Common Stock Purchase Agreements, with certain new and existing investors who previously delivered non-binding indications of interest to us to participate in a financing of up to $8 million in connection with the Merger with Essentialis. Under the terms of the Common Stock Purchase Agreements, we agreed to sell to the purchasers, in a private placement, an aggregate of 1,666,666 shares of common stock, par value $0.001 per share, at a purchase price of $4.80 per share for gross proceeds of approximately $8 million, or the Concurrent Financing. The Concurrent Financing closed concurrently with the closing of the Merger on March 7, 2017. In accordance with the Merger Agreement, Company E Merger Sub, Inc. was merged with and into Essentialis, with Essentialis as the surviving corporation and wholly-owned subsidiary of us.

Under the terms of the Merger Agreement, in connection with the closing of the transactions contemplated by the Merger Agreement, the former holders of Essentialis stock received an aggregate of 3,788,388 shares of our common stock. At the closing, we held back an aggregate of 182,678 shares of common stock as partial recourse to satisfy indemnification claims made by us under the Merger Agreement, and such shares of common stock were issued to Essentialis stockholders on the one year anniversary of the closing (subject to the limitations set forth in the Merger Agreement). We also were obligated to issue an additional 913,389 shares of our common stock to Essentialis stockholders upon the achievement of a development milestone associated with Essentialis' product, which shares were issued in May 2018. Following the issuance of the shares held back by us and assuming that we issue all of the shares of common stock upon the achievement of the development milestone, we would issue a total of 4,879,455 shares of common stock 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, we are obligated to make cash earnout payments of up to a maximum of $35 million to Essentialis stockholders. The merger consideration described above will be reduced by any such shares of our 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.

Certain members of our board of directors, including Drs. Shah and Collinson, were affiliates to investors in the Concurrent Financing and stockholders of Essentialis entitled to a portion of the Merger consideration:

- Entities affiliated with Vivo Ventures, which are affiliated with Drs. Engleman and Shah, purchased 282,092 shares of common stock in the Concurrent Financing (approximately 16.9% of the shares of common stock issued in the Concurrent Financing for an aggregate investment of $1,354,043.16) and received 1,165,563 shares (approximately 30.8% of the shares of common stock issued to Essentialis stockholders in the Merger at an aggregate value of $3,962,914.20). Additionally, Dr. Shah received an aggregate of $82,949.12 of the Merger consideration as a participant in Essentialis' management carve-out plan.
- Entities affiliated with Forward Ventures, which is affiliated with Dr. Collinson purchased 284,661 shares of common stock in the Concurrent Financing (approximately 17.1% of the shares of common stock issued in the Financing) for an aggregate investment of $1,366,374.20 and received 1,165,684 shares (approximately 30.8% of the shares of common stock issued to Essentialis stockholders in the Merger) at an aggregate value of $3,963,325.60.

Equity Awards to Executive Officers

We have granted, and will in the future grant, stock options and other equity awards to our named executive officers, other executive officers and certain of our directors. See the sections of this prospectus entitled "Management — Non-Employee Director Compensation" and "Executive Compensation."

Indemnification Agreements

We have also entered into indemnification agreements with our directors and certain of our executive officers. The indemnification agreements and our certificate of incorporation and bylaws require us to indemnify our directors and officers to the fullest extent permitted by Delaware law.

Policies and Procedures for Related Party Transactions

We have adopted a policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our common stock and any members of the immediate family of any of the foregoing persons are not permitted to enter into a related person transaction with us without the prior consent of our audit committee. Any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of any class of our common stock or any member of the immediate family of any of the foregoing persons in which the amount involved exceeds $120,000 and such person would have a direct or indirect interest must first be presented to our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our audit committee is to consider the material facts of the transaction, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT OF SOLENO THERAPEUTICS

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of March 14, 2019, for:

- each of our directors;
- each of our named executive officers;
- all of our current directors and executive officers as a group; and
- each person, or group of affiliated persons, who beneficially owned more than 5% of Soleno Therapeutics common stock.

We have determined beneficial ownership in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares of our common stock that they beneficially owned, subject to applicable community property laws.

Applicable percentage ownership is based on 31,755,169 shares of our common stock outstanding as of March 14, 2019.

Unless otherwise indicated below, the address of each beneficial owner listed in the table below is care of Soleno Therapeutics, Inc., 1235 Radio Road, Suite 110, Redwood City, California 94065. Beneficial ownership representing less than 1% is denoted with an asterisk (*).

	Shares Beneficially Owned	
Name of Beneficial Owner	**Number of Shares**	**%**
5% Stockholders		
Entities Associated with Jack W. Schuler (1)	5,675,238	17.26%
Entities Associated with Oracle Partners, LP (2)	5,485,558	16.41%
Entities Associated with Vivo Ventures Fund V, LP (3)	5,411,650	16.49%
Abingworth Bioventures VII LP (4)	4,669,272	14.70%
Forward Ventures V, L.P. (5)	1,802,901	5.68%
Technology Partners VII (6)	1,692,627	5.33%
Named Executive Officers and Directors:		
Andrew Sinclair (4) (7)	4,670,938	14.71%
Stuart Collinson (5) (8)	1,814,097	5.71%
Ernest Mario (9)	1,107,965	3.46%
Anish Bhatnagar (10)	679,014	2.10%
Kristen Yen (11)	90,525	*
Mahendra Shah (12)	59,924	*
William G. Harris (13)	51,785	*
Jonathan Wolter (14)	18,625	*
All current directors and executive officers as a group (8 Persons) (15)	8,492,873	25.88%

* Represents beneficial ownership of less than one percent (1%).

(1) Represents shares of common stock outstanding or issuable within 60 days of March 14, 2019, upon the exercise of options or warrants: 5,675,238 shares of common stock held by the Jack W. Schuler Living Trust, consisting of (i) 4,550,678 outstanding shares of common stock and (ii) 1,124,560 shares of common stock issuable upon the exercise of warrants.

(2) Represents shares of common stock outstanding or issuable within 60 days of March 14, 2019, upon the exercise of options or warrants: (a) 2,615,481 outstanding shares of common stock held by Oracle Partners LP (b) 855,243 outstanding shares of common stock held by Oracle Ten Fund, LP; (c) 342,834 outstanding shares of common stock held by Oracle Institutional Partners LP; and (d) 1,672,000 shares of common issuable upon the exercise of warrants held by Oracle Investment Management.

(3) Represents shares of common stock outstanding or issuable within 60 days of March 14, 2019, upon the exercise of options or warrants: (a) 5,255,432 shares of common stock held by Vivo Ventures Fund, V, L.P., consisting of (i) 4,210,492 outstanding shares of common stock and (ii) 1,044,940 shares of common stock issuable upon the exercise of warrants; (b) 61,718 shares of common stock held by Vivo Ventures V Affiliates Fund, LP., consisting of (i) 49,456 outstanding shares of common stock and (ii) 12,262 shares of common stock issuable upon the exercise of warrants; (c) 14,080 outstanding shares of common stock held by Vivo Capital, LLC.; (d) 46,254 shares of common stock held by BDF IV Annex Fund, L.P., consisting of (i) 45,413 outstanding shares of common stock and (ii) 841 shares of common stock issuable upon the exercise of warrants; (e) 33,588 shares of common stock held by Biotechnology Development Fund IV, L.P., consisting of (i) 33,388 outstanding shares of common stock and (ii) 200 shares of common stock issuable upon the exercise of warrants; and (f) 618 shares of common stock held by Biotechnology Development Fund IV Affiliates, L.P., consisting of (i) 615 outstanding shares of common stock and (ii) 3 shares of common stock issuable upon the exercise of warrants. Vivo Ventures V Fund LLC (Vivo V LLC), is the sole general partner of both of Vivo Ventures Fund V, L.P. and Vivo Ventures V Affiliates Fund, L.P. (Vivo V Funds), and may be deemed to beneficially own the common stock of Soleno Therapeutics owned by the Vivo V Funds. Vivo Capital LLC is the management company of Vivo V LLC. Vivo V LLC disclaims beneficial ownership of the shares of Soleno Therapeutics held by each of the Vivo V Funds, except to the extent of its pecuniary interest therein. BioAsia Investments IV, LLC (BAI IV), is the sole general partner of Biotechnology Development Fund IV, LP, Biotechnology Development Fund IV Affiliates, L.P., BDF IV Annex Fund, L.P. (BDF IV Funds) and may be deemed to beneficially own the common stock of Soleno Therapeutics owned by the BDF IV Funds. BAI IV disclaims beneficial ownership of the shares of Soleno Therapeutics held by each of the BDF IV Funds, except to the extent of its pecuniary interest therein. BioAsia Management, LLC (BAM), is the sole general partner of Biotechnology Development Fund II, L.P. (BDF II), and may be deemed to beneficially own the common stock of

Soleno Therapeutics owned by BDF II. BAM disclaims beneficial ownership of the shares of Soleno Therapeutics held by each of the BDF II Funds, except to the extent of its pecuniary interest therein.

(4) Represents shares of common stock outstanding or issuable within 60 days of March 14, 2109, upon the exercise of options: consisting of (a) 4,669,272 outstanding shares of common stock held by Abingworth Bioventures VII LLP, and (b) 1,666 shares of common stock subject to outstanding options granted to Dr. Andrew Sinclair, and held by him on behalf of Abingworth LLP, that are vested and exercisable within sixty days of March 14, 2019. A Schedule 13G filed on December 27, 2018 reports voting and dispositive power over these shares. Dr. Sinclair disclaims beneficial ownership in all shares held by Abingworth LLP except to the extent of his pecuniary interest therein.

(5) Represents 1,802,901 outstanding shares of common stock held by Forward Ventures V, L.P., or Forward Ventures. Stuart Collinson is a managing member of Forward Ventures and has shared voting power over the shares of common stock beneficially owned by Forward Ventures.

(6) Represents 1,692,627 outstanding shares of common stock held by Technology Partners VII.

(7) Represents shares of common stock outstanding or issuable within 60 days of March 14, 2019, upon the exercise of options or warrants: 4,670,938 shares of common stock held by Dr. Sinclair, consisting of (i) the shares held by Abingworth Bioventures VII LP as set forth above in footnote 4 and (ii) 1,666 shares of common stock subject to outstanding options that are vested and exercisable within 60 days of March 14, 2019.

(8) Represents shares of common stock outstanding or issuable within 60 days of March 14, 2019, upon the exercise of options or warrants: 1,814,097 shares of common stock held by Dr. Collinson, consisting of (i) the shares held by Forward Ventures V, LP as set forth above in footnote 5 and (ii) 11,196 shares of common stock subject to outstanding options that are vested and exercisable within sixty days of March 14, 2019.

(9) Represents shares of common stock outstanding or issuable within 60 days of March 14, 2019, upon the exercise of options or warrants: (a) 794,599 shares of common stock held by Dr. Mario, consisting of (i) 497,216 shares of outstanding common stock, (ii) 27,799 shares of common stock subject to outstanding options that are vested and exercisable within sixty days of March 14, 2019, (iii) 269,584 shares of common stock issuable upon the exercise of warrants; (b) 311,283 outstanding shares of common stock held by Mildred M. Mario Fifteen Year Residence Trust; and (c) 2,083 outstanding shares of common stock held by Mildred M. Mario.

(10) Represents shares of common stock outstanding or issuable within 60 days of March 14, 2019, upon the exercise options or warrants: 679,014 shares of common stock held by Dr. Bhatnagar, consisting of (i) 64,578 outstanding shares of common stock and (ii) 614,436 shares of common stock subject to outstanding options that are vested and exercisable within sixty days of March 14, 2019.

(11) Represents shares of common stock outstanding or issuable within 60 days of March 14, 2019, upon the exercise of options or warrants: 90,525 shares of common stock held by Ms. Yen, consisting of (i) 16,691 outstanding shares of common stock and (ii) 73,834 shares of common stock subject to outstanding options that are vested and exercisable within sixty days of March 14, 2019.

(12) Represents shares of common stock outstanding or issuable within 60 days of March 14, 2019, upon the exercise of options or warrants: 59,924 shares of common stock held by Dr. Shah, consisting of (i) 48,728 outstanding shares of common stock and (ii) 11,196 shares of common stock subject to outstanding options that are vested and exercisable within sixty days of March 14, 2019.

(13) Represents shares of common stock outstanding or issuable within 60 days of March 14, 2019, upon the exercise of options or warrants: 51,785 shares of common stock held by Mr. Harris, consisting of (i) 33,941 outstanding shares of common stock and (ii) 17,844 shares of common stock subject to outstanding options that are vested and exercisable within sixty days of March 14, 2019.

(14) Represents shares of common stock outstanding or issuable within 60 days of March 14, 2019, upon the exercise of options or warrants: 18,625 shares of common stock held by Mr. Wolter, consisting of 18,625 shares of common stock subject to outstanding options that are vested and exercisable within sixty days of March 14, 2019.

(15) In total, 1,059,042 of these shares are attributable to options and warrants currently exercisable or exercisable within 60 days of March 14, 2019.

DESCRIPTION OF SECURITIES

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.

The following description of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to our amended and restated certificate of incorporation and our amended and restated bylaws. Copies of these documents were filed with the SEC as exhibits to our registration statement in connection with our IPO.

As of March 14, 2019, we had 31,755,169 outstanding shares of our common stock. As of March 14, 2019, we also had 2,131,153 outstanding options to acquire shares of our common stock, having a weighted-average exercise price of $6.03 per share. As of March 14, 2019, we had outstanding 1,189,366 warrants to purchase common stock and 120,421 warrants to purchase common stock issued prior to our IPO and 6,024,425 outstanding warrants from the 2017 PIPE Offering and 513,617 outstanding warrants from the 2018 PIPE Offering.

Common stock

There were 31,755,169 shares of common stock issued and outstanding as of March 14, 2019.

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. All shares of common stock that are outstanding as of the date of this prospectus will be fully-paid and non-assessable.

Series A Warrants Issued as Part of the Units in our IPO

The Series A Warrants entitle the registered holder to purchase one share of our common stock at an expected exercise price equal to $32.50 per share, subject to adjustment as discussed below, at any time up to 5:00 p.m., New York City time, on the five-year anniversary of the date of issuance, which is November 12, 2019.

The Series A Warrants have been issued in registered form under a warrant agreement between us and our warrant agent. The material provisions of the warrants are set forth herein but are only a summary and are qualified in their entirety by the provisions of each of the warrant agreements that have been filed as exhibits to the registration statement, of which this prospectus forms a part.

The exercise price and number of shares of common stock issuable upon exercise of the Series A 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 Series A Warrants will not be adjusted for issuances of common stock at a price below their respective exercise prices.

The Series A Warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the warrant agent, with the exercise form on the reverse side of the warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price, as applicable, by certified or official bank check payable to us, for the number of warrants being exercised. Under the terms of each of the warrant agreements, we have agreed to use our best efforts to maintain the effectiveness of the registration statement and current prospectus relating to common stock issuable upon exercise of the Series A Warrants until the expiration of the Series A Warrants.

During any period we fail to have maintained an effective registration statement covering the shares underlying the Series A Warrants, the warrant holder may exercise the Series A Warrants on a cashless basis. The warrant holders do not have the rights or privileges of holders of common stock, nor any voting rights, until they exercise their Series A Warrants and receive shares of common stock. After the issuance of shares of common stock upon exercise of the Series A Warrants, each holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.

No fractional shares of common stock will be issued upon exercise of the Series A Warrants. If, upon exercise of the Series A Warrants, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, round up to the nearest whole number of shares of common stock to be issued to the warrant holder. If multiple Series A Warrants are exercised by the holder at the same time, we will aggregate the number of whole shares issuable upon exercise of all the Series A Warrants.

Our Series A Warrants are listed on the NASDAQ Capital Market under the symbol "SLNOW".

In addition, the Series A Warrants will not be exercisable to the extent that, after exercise, a holder and/or its affiliates would beneficially own more than 4.99% of the common stock outstanding immediately after giving effect to such exercise; provided, however, that if a holder and/or its affiliates already own 4.99% on the date of the exercise, then such limitation will not apply.

We will use our reasonable best efforts to maintain an effective registration statement and prospectus covering the number of shares of common stock issuable upon exercise of the Series A Warrants at any time that these Series A Warrants are exercisable.

Series C Warrants

The Series C Warrants were issued on March 5, 2015 pursuant to a private transaction, or the Private Transaction, pursuant to a Warrant Exercise Agreement, or the Warrant Exercise Agreement, with certain holders of our Series B Warrants, and pursuant to an exchange offer, or the Exchange Offer, entitle the registered holder to purchase one share of our common stock at an expected exercise price equal to $31.25 per share, subject to adjustment as discussed below, at any time commencing upon issuance of the Series C Warrants and terminating at 5:00 p.m., New York City time, on March 4, 2020.

The Series C Warrants have been issued in registered form under a warrant agreement between us and our warrant agent. The material provisions of the Series C Warrants are set forth herein but are only a summary and are qualified in their entirety by the provisions of each of the warrant agreements that have been filed as exhibits to the registration statement, of which this prospectus forms a part.

The exercise price and number of shares of common stock issuable upon exercise of the Series C 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 Series C Warrants will not be adjusted for issuances of common stock at a price below its exercise price.

The Series C Warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the warrant agent, with the exercise form on the reverse side of the warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price, as applicable, by certified or official bank check payable to us, for the number of warrants being exercised.

A registration statement on Form S-1 relating to the resale of the shares of common stock issuable upon exercise of the Series C Warrants issued in the Private Transaction was declared effective on May 19, 2015. In connection with the Private Transaction, we relied on the exemption from registration provided by Section 4(a)(2) of the Securities Act for transactions not involving a public offering, and Rule 506 of Regulation D thereunder as a private offering, without general solicitation, made only to and with accredited investors. We filed a Notice of Exempt Offering on Form D on March 11, 2015 covering the Private Transaction and the Series C Warrants. The resale of the shares of common stock issuable upon exercise of the Series C Warrants issued in the Exchange Offer are covered by a registration statement on Form S-4, which was declared effective on June 25, 2015.

The holders of the Series C Warrants do not have the rights or privileges of holders of common stock, nor any voting rights, until they exercise their Series C Warrants and receive shares of common stock. After the issuance of shares of common stock upon exercise of the Series C Warrants, each such holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.

No fractional shares of common stock will be issued upon exercise of the Series C Warrants. If, upon exercise of the Series C Warrants, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, round up to the nearest whole number of shares of common stock to be issued to such warrant holder. If multiple Series C Warrants are exercised by a Series C Warrant holder at the same time, we will aggregate the number of whole shares issuable upon exercise of all Series C Warrants.

The Series C Warrants are not listed on the NASDAQ Capital Market or any other securities exchange.

Series D Common Stock Purchase Warrants

The Series D Common Stock Purchase Warrants were originally issued in the private placement entered into on October 12, 2015, pursuant to the 2015 Sabby Purchase Agreement. In connection with the purchase of Series B Convertible Preferred Stock pursuant to the Sabby Purchase Agreement, we amended the Series D Common Stock Purchase Warrants and reduced the per share exercise price from $12.30 per share to $8.75 per share. Following amendment, the amended Series D Common Stock Purchase Warrants entitle the holders thereof to purchase one share of our common stock underlying each Series D Common Stock Purchase Warrant, at an exercise price equal to $8.75 per share, subject to adjustment as discussed below, at any time commencing upon April 15, 2016 through October 15, 2021.

The Series D Common Stock Purchase Warrants have been issued in certificated form under a warrant agreement between us and our warrant agent. The material provisions of the Series D Common Stock Purchase Warrants are set forth herein but are only a summary and are qualified in their entirety by the provisions of each of the form of Series D Common Stock Purchase Warrant that have been filed as exhibits to the registration statement, of which this prospectus forms a part.

The exercise price and number of shares of common stock issuable upon exercise of the Series D Common Stock Purchase 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 Series D Common Stock Purchase Warrants will not be adjusted for issuances of common stock at a price below its exercise price.

The Series D Common Stock Purchase Warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the warrant agent, with the exercise form on the reverse side of the warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price, as applicable, by certified or official bank check payable to us, for the number of warrants being exercised.

A registration statement on Form S-1 relating to the resale of the shares of common stock issuable upon exercise of the Series D Warrants was declared effective on January 4, 2016. In connection with the Sabby Purchase Agreement, we relied on the exemption from registration provided by Section 4(a)(2) of the Securities Act for transactions not involving a public offering, and Rule 506 of Regulation D thereunder as a private offering, without general solicitation, made only to and with accredited investors. We filed a Notice of Exempt Offering on Form D on October 22, 2015 covering the securities sold pursuant to the Sabby Purchase Agreement.

The holders of the Series D Common Stock Purchase Warrants do not have the rights or privileges of holders of common stock, nor any voting rights, until they exercise their Series D Common Stock Purchase Warrants and receive shares of common stock. After the issuance of shares of common stock upon exercise of the Series D Common Stock Purchase Warrants, each such holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.

No fractional shares of common stock will be issued upon exercise of the Series D Common Stock Purchase Warrants. If, upon exercise of the Series D Common Stock Purchase Warrants, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, round up to the nearest whole number of shares of common stock to be issued to such warrant holder. If multiple Series D Common Stock Purchase Warrants are exercised by a Series D Common Stock Purchase Warrants holder at the same time, we will aggregate the number of whole shares issuable upon exercise of all Series D Common Stock Purchase Warrants.

The Series D Common Stock Purchase Warrants are not, and will not be, listed on the NASDAQ Capital Market or any other securities exchange.

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

The 2017 PIPE Warrants were issued on December 15, 2017 in to the 2017 PIPE Offering, pursuant to a Warrant Agreement, with each of the selling stockholders, entitle the registered holder to purchase one share of our common stock at an expected 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 5:00 p.m., New York City time, on (i) December 15, 2020 and (ii) 30 days following positive Phase III results for Diazoxide Choline Controlled-Release (DCCR) tablet in Prader-Willi syndrome (PWS).

The 2017 PIPE Warrants have been issued in registered form under a warrant agreement between us and our warrant agent. The material provisions of the 2017 PIPE Warrants are set forth herein but are only a summary and are qualified in their entirety by the provisions of each of the warrant agreements that have been filed as exhibits to the registration statement, of which this prospectus forms a part.

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.

The 2017 PIPE Warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the warrant agent, with the exercise form on the reverse side of the warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price, as applicable, by certified or official bank check payable to us, for the number of warrants being exercised.

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.

In connection with the 2017 PIPE Offering, we relied on the exemption from registration provided by Section 4(a)(2) of the Securities Act for transactions not involving a public offering, and Rule 506 of Regulation D thereunder as a private offering, without general solicitation, made only to and with accredited investors. We filed a Notice of Exempt Offering on Form D on December 22, 2017 covering the 2017 PIPE Offering and the 2017 PIPE Warrants. The shares of common stock issuable upon exercise of the 2017 PIPE Warrants issued in the 2017 PIPE Offering are being registered in this offering.

The holders of the 2017 PIPE Warrants do not have the rights or privileges of holders of common stock, nor any voting rights, until they exercise their 2017 PIPE Warrants and receive shares of common stock. After the issuance of shares of common stock upon exercise of the 2017 PIPE Warrants, each such holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.

No fractional shares of common stock will be issued upon exercise of the 2017 PIPE Warrants. If, upon exercise of the 2017 PIPE Warrants, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, round up or down to the nearest whole number of shares of common stock to be issued to such warrant holder. If multiple 2017 PIPE Warrants are exercised by a 2017 PIPE Warrant holder at the same time, we will aggregate the number of whole shares issuable upon exercise of all 2017 PIPE Warrants.

The 2017 PIPE Warrants are not listed on the NASDAQ Capital Market or any other securities exchange.

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

The 2018 PIPE Warrants were issued on December 19, 2018 in to the 2018 PIPE Offering, pursuant to a Warrant Agreement, with each of the selling stockholders, entitle the registered holder to purchase one share of our common stock at an expected exercise price equal to $2.00 per share, subject to adjustment as discussed below, at any time commencing upon May 19, 2019 and terminating at the earlier of 5:00 p.m., New York City time, on December 19, 2023.

The 2018 PIPE Warrants have been issued in registered form under a warrant agreement between us and our warrant agent. The material provisions of the 2018 PIPE Warrants are set forth herein but are only a summary and are qualified in their entirety by the provisions of each of the warrant agreements that have been filed as exhibits to the registration statement, of which this prospectus forms a part.

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.

The 2018 PIPE Warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the warrant agent, with the exercise form on the reverse side of the warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price, as applicable, by certified or official bank check payable to us, for the number of warrants being exercised.

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.

In connection with the 2018 PIPE Offering, we relied on the exemption from registration provided by Section 4(a)(2) of the Securities Act for transactions not involving a public offering, and Rule 506 of Regulation D thereunder as a private offering, without general solicitation, made only to and with accredited investors. The shares of common stock issuable upon exercise of the 2018 PIPE Warrants issued in the 2018 PIPE Offering are being registered in this offering.

The holders of the 2018 PIPE Warrants do not have the rights or privileges of holders of common stock, nor any voting rights, until they exercise their 2018 PIPE Warrants and receive shares of common stock. After the issuance of shares of common stock upon exercise of the 2018 PIPE Warrants, each such holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.

No fractional shares of common stock will be issued upon exercise of the 2018 PIPE Warrants. If, upon exercise of the 2018 PIPE Warrants, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, round up or down to the nearest whole number of shares of common stock to be issued to such warrant holder. If multiple 2018 PIPE Warrants are exercised by a 2018 PIPE Warrant holder at the same time, we will aggregate the number of whole shares issuable upon exercise of all 2018 PIPE Warrants.

The 2018 PIPE Warrants are not listed on the NASDAQ Capital Market or any other securities exchange.

Other Outstanding Options and Warrants

As of March 14, 2019, we had outstanding options to purchase 2,131,153 shares of our common stock and outstanding warrants to purchase an aggregate of 7,847,829 shares of our common stock.

Convertible Preferred Stock

We are authorized to issue 10,000,000 shares of our Convertible Preferred Stock. Our board of directors has the authority, without further action by our stockholders, to issue these shares of Convertible Preferred Stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding. Our board of directors may authorize the issuance of Convertible Preferred Stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The purpose of authorizing our board of directors to issue Convertible Preferred Stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of Convertible Preferred Stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of us and may adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. It is not possible to state the actual effect of the issuance of any shares of Convertible Preferred Stock on the rights of holders of common stock until the board of directors determines the specific rights attached to that Convertible Preferred Stock.

Certificate of Designation and Series B Convertible Preferred Stock

Redemption under the Series B Convertible Preferred Stock Purchase Agreement

On July 5, 2016, in connection with the initial sale of Series B Convertible Preferred Stock pursuant to the Sabby Purchase Agreement, we redeemed 355 shares of Series A Convertible Preferred Stock, representing approximately 192,324 shares of common stock on an as-converted basis, for an aggregate price of $1,799,012.

Following the second closing under the Sabby Purchase Agreement, we redeemed the remaining 1,200 shares of Series A Convertible Preferred Stock held by Sabby, representing approximately 648,756 shares of common stock on an as-converted basis, for an aggregate price of $6,000,988.

Certificate of Designation and Series B Convertible Preferred Stock.

On June 29, 2016, we filed a Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock, or the Certificate of Designation, with the Secretary of State of the State of Delaware. The number of shares of Series B Convertible Preferred Stock designated is 13,780, and each share of our Series B Convertible Preferred Stock has a stated value equal to $1,000. Under the terms of the Series B Convertible Preferred Stock, we cannot issue any shares of common stock to Sabby, and Sabby cannot convert the Series B Convertible Preferred Stock into common stock, to the extent it would result in ownership in excess of 4.99%.

Voting Rights.

Except as otherwise provided herein or as otherwise required by law, the Series B Convertible Preferred Stock shall have no voting rights. However, as long as any shares of Series B Convertible Preferred Stock are outstanding, we shall not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series B Convertible Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series B Convertible Preferred Stock or alter or amend the Certificate of Designation, (b) amend our certificate of incorporation or other charter documents in any manner that adversely affects any rights of the holders of Series B Convertible Preferred Stock, (c) increase the number of authorized shares of Series B Convertible Preferred Stock, or (d) enter into any agreement with respect to any of the foregoing.

Liquidation.

Upon any liquidation, dissolution or winding-up of our company, whether voluntary or involuntary that is not a Fundamental Transaction (as defined in our Certificate of Designation), the holders of Series B Convertible Preferred Stock shall be entitled to receive out of the assets, whether capital or surplus, of our company the same amount that a holder of common stock would receive if the Series B Convertible Preferred Stock were fully converted (disregarding for such purposes any conversion limitations hereunder) to common stock which amounts shall be paid on a pari passu basis with all holders of common stock.

Conversion Price.

The conversion price for the Series B Convertible Preferred Stock shall equal $1.00, subject to certain terms as described in the Certificate of Designation.

Registration Rights

Stockholder registration rights

We are party to an investor rights agreement which provides that holders of shares of our convertible preferred stock have certain registration rights, as set forth below. The investor rights agreement has been amended or restated from time to time in connection with our preferred stock financings, most recently as of March 20, 2008. The registration of shares of our common stock pursuant to the exercise of registration rights described below would enable the holders to sell these shares without restriction under the Securities Act, when the applicable registration statement is declared effective. We will pay the registration expenses, other than underwriting discounts and commissions, of the shares registered pursuant to the demand, piggyback and Form S-3 registrations described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions, to limit, or exclude entirely, the number of shares such holders may include. The demand, piggyback and Form S-3 registration rights described below terminate upon the earliest to occur of: (i) the date that is four years after the closing of our IPO; (ii) with respect to each holder of convertible preferred stock, at such time as all such shares can be sold in a three-month period without registration in compliance with Rule 144; (iii) with respect to each stockholder, the date that the stockholder no longer holds any shares that carry these registration rights; or (iv) following termination of the investor rights agreement.

Demand registration rights

Certain holders of our common stock, which was issued upon the conversion of outstanding convertible preferred stock that occurred in connection with our IPO, are entitled to certain demand registration rights. The holders of a majority of these shares may, on not more than two occasions, request that we file a registration statement having an aggregate offering price to the public of not less than $7,500,000 (net of underwriting discounts and commissions) to register all or a portion of their shares.

Piggyback registration rights

Certain holders of our common stock, which was issued upon the conversion of outstanding convertible preferred stock in connection with our IPO, are entitled to, and the necessary percentage of holders waived, their rights to include their shares of registrable securities in our IPO. In the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, the holders of these shares will be entitled to certain “piggyback” registration rights allowing them to include their shares in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act, including a registration statement on Form S-3 as discussed below, other than with respect to a demand registration or a registration statement on Forms S-4 or S-8, the holders of these shares are entitled to notice of the registration and have the right, subject to limitations that the underwriters may impose on the number of shares included in the registration, to include their shares in the registration. However, in no event shall the amount of securities of the selling stockholders included in the offering be reduced below thirty percent of the total amount of securities included in such offering, unless the offering is the initial public offering of our securities, in which case all shares may be excluded entirely.

Form S-3 registration rights

Certain holders of our common stock, which was issued upon the conversion of outstanding convertible preferred stock that occurred in connection with our IPO, are entitled to certain Form S-3 registration rights, provided that we have not already effected one such registration within the twelve-month period preceding the date of such request. Such holders may make a request that we register their shares on Form S-3 if we are qualified to file a registration statement on Form S-3. Such request for registration on Form S-3 must cover securities the aggregate offering price of which, net of underwriting discounts and commissions, is at least $1,000,000.

2018 PIPE Offering Rights on Form S-1

Pursuant to the Unit Purchase Agreement, we agreed to provide certain registration rights to the selling stockholders, including filing one or more registration statements as permissible and necessary to register shares of common stock and the shares of common stock underlying the 2018 Warrant Shares under the Securities Act, which shares are being registered in this offering.

2017 PIPE Offering Rights on Form S-1

Pursuant to the Unit Purchase Agreement, we agreed to provide certain registration rights to the selling stockholders, including filing one or more registration statements as permissible and necessary to register the 2017 Resale Shares under the Securities Act. The corresponding registration statement on Form S-1 became effective on February 6, 2018.

2017 Aspire Capital Registration Rights on Form S-1

Concurrently with entering into a Common Stock Purchase Agreement on January 27, 2017, or the 2017 Aspire Purchase Agreement, with Aspire Capital, LLC, or Aspire Capital, we also entered into a Registration Rights Agreement with Aspire, in which we agreed to file one or more registration statements as permissible and necessary to register under the Securities Act, the sale of the shares of our common stock that have been and may be issued under the 2017 Aspire Purchase Agreement. The corresponding registration statement on Form S-1 became effective on February 14, 2017. The 2017 Aspire Purchase Agreement was terminated upon the closing of the 2017 PIPE Offering.

2015 Aspire Capital Registration Rights on Form S-1

Concurrently with entering into a Common Stock Purchase Agreement on July 24, 2015, or the 2015 Aspire Purchase Agreement, with Aspire Capital, we also entered into a Registration Rights Agreement with Aspire, in which we agreed to file one or more registration statements as permissible and necessary to register under the Securities Act, the sale of the shares of our common stock that have been and may be issued under the 2015 Aspire Purchase Agreement. The corresponding registration statement on Form S-1 became effective on August 11, 2015.

2015 Sabby Registration Rights on Form S-1

Concurrently with entering into the 2015 Securities Purchase Agreement with Sabby, we also entered into a Registration Rights Agreement with Sabby, in which we agreed to file one or more registration statements as permissible and necessary to register under the Securities Act, the sale of the shares of our common stock that have been and may be issued to under the 2015 Sabby Purchase Agreement, including upon the conversion of Series A Convertible Preferred Stock, or the exercise of Series D Common Stock Purchase Warrants or certain warrants to purchase Common Stock issued to placement agent for the 2015 private placement transaction pursuant to the 2015 Sabby Purchase Agreement, which we refer to as our 2015 Placement Agent Warrants. The corresponding registration statement on Form S-1 became effective on January 4, 2016.

2016 Sabby Registration Rights on Form S-1

Concurrently with entering into a Securities Purchase Agreement on June 29, 2016, or the Sabby Purchase Agreement, with Sabby, we also entered into a Registration Rights Agreement with Sabby, in which we agreed to file one or more registration statements as permissible and necessary to register under the Securities Act, the sale of the shares of our common stock that have been and may be issued to under the Sabby Purchase Agreement, including upon the conversion of Series B Convertible Preferred Stock or Placement Agent Warrants. The corresponding registration statement on Form S-1 became effective on September 23, 2016.

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.

The corresponding registration statement on Form S-1 became effective. We list our common stock and the Series A Warrants on the NASDAQ Capital Market under the trading symbols “SLNO” and “SLNOW,” respectively. The Series B Warrants, Series C Warrants, Series D Common Stock Purchase Warrants, 2015 Placement Agent Warrants, the Series A Convertible Preferred Stock, the Series B Convertible Preferred Stock, the Placement Agent Warrants, the 2017 PIPE Warrants and the 2018 PIPE Warrants are not listed on any trading market.

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, Series A Warrants, Series B Warrants, Series C Warrants, Series D Common Stock Purchase Warrants, 2015 Placement Agent Warrants, Series B Convertible Preferred Stock, Placement Agent Warrants, 2017 PIPE Warrants and the 2018 PIPE Warrants is American Stock Transfer & Trust Company, LLC.

LEGAL MATTERS

Wilson Sonsini Goodrich & Rosati, Professional Corporation, Palo Alto, CA, will pass upon the validity of the shares of common stock offered hereby. Certain members of, and investment partnerships comprised of members of, and persons associated with, Wilson Sonsini Goodrich & Rosati own an interest representing less than 0.5% of our common stock.

EXPERTS

Marcum LLP, an independently registered public accounting firm has audited our financial statements as of and for each of the years in the two-year period ended December 31, 2018, as set forth in their report which includes an explanatory paragraph as to the Company's ability to continue as a going concern, dated March 19, 2019. We have included our financial statements in the prospectus and elsewhere in the registration statement in reliance on the report of Marcum LLP, given their authority as experts in accounting and auditing.

AVAILABLE INFORMATION

We have filed with the SEC a Registration Statement on Form S-1 under the Securities Act in connection with this offering of our common stock by our selling stockholders. This Prospectus, which constitutes a part of the Registration Statement, does not contain all of the information set forth in the registration statement, some items of which are contained in exhibits to the Registration Statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the Registration Statement, including the exhibits and the financial statements and notes filed as a part of the Registration Statement. Statements contained in this Prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the Registration Statement, please see the copy of the contract or document that has been filed. Each statement in this Prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The exhibits to the Registration Statement should be referenced for the complete contents of these contracts and documents. A copy of the Registration Statement and the exhibits filed therewith may be inspected without charge at the public reference room of the SEC, located at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may obtain information on the operation of the public reference rooms by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website that contains reports, proxy statements, and other information about issuers, like us, that file electronically with the SEC. The address of that website is *www.sec.gov.*

We are subject to the information and reporting requirements of the Exchange Act and, in accordance with this law, we file periodic reports, proxy statements, and other information with the SEC. These periodic reports, proxy statements, and other information are available for inspection and copying at the SEC's public reference facilities and the website of the SEC referred to above. We also maintain a website at *www.soleno.life*. You may access our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website (*www.soleno.life*) as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not incorporated by reference into this Prospectus.

INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Section 145 of the Delaware General Corporation Law, or the Delaware Law, provides that a corporation may indemnify directors and officers as well as other employees and individuals against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement in connection with specified actions, suits or proceedings, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation — a "derivative action"), if they acted in good faith and in a manner they reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe their conduct was unlawful. A similar standard is applicable in the case of derivative actions, except that indemnification only extends to expenses (including attorneys' fees) incurred in connection with defense or settlement of such action, and the statute requires court approval before there can be any indemnification where the person seeking indemnification has been found liable to the corporation. Under Section 145 of the Delaware Law, a corporation shall indemnify an agent of the corporation for expenses actually and reasonably incurred if and to the extent such person was successful on the merits in a proceeding or in defense of any claim, issue or matter therein.

Section 145 of the Delaware Law authorizes a court to award, or a corporation's board of directors to grant, indemnity to directors and officers in terms sufficiently broad to permit such indemnification under certain circumstances for liabilities (including reimbursement for expenses incurred) arising under the Securities Act of 1933, as amended. Our amended and restated certificate of incorporation and bylaws provide for indemnification of our directors, officers, employees and other agents to the maximum extent permitted by the Delaware Law. We have also entered into agreements with its directors and officers that will require us, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers to the fullest extent not prohibited by law. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers or persons controlling our company pursuant to such provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

There is no litigation pending or, to the best of our knowledge, threatened which might or could result in a claim for indemnification by a director or officer.

PLAN OF DISTRIBUTION

We are registering the shares of common stock issued to the selling stockholders and issuable upon exercise of the warrants issued to the selling stockholders to permit the resale of these shares of common stock by the selling stockholders from time to time from after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling stockholders of the shares of common stock. We will bear all fees and expenses incident to our obligation to register the shares of common stock.

Each selling stockholder may, from time to time, sell any or all of their shares of common stock covered hereby on The NASDAQ Capital Market or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or privately negotiated prices. A selling stockholder may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales, to the extent permitted by law;
- in transactions through broker-dealers that agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell the shares of common stock under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440-1.

In connection with the sale of the shares of common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the shares of common stock in the course of hedging the positions they assume. The selling stockholders may also sell the shares of common stock short and deliver these securities to close out their short positions or to return borrowed shares in connection with such short sales, or loan or pledge the shares of common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares of common stock offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling stockholders and any broker-dealers or agents that are involved in selling the shares of common stock may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such selling stockholders, broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Selling stockholders who are “underwriters” within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act and may be subject to certain statutory liabilities of, including but not limited to, Sections 11, 12 and 17 of the Securities Act and Rule 10b-5 under the Exchange Act. Each selling stockholder has informed us that it is not a registered broker-dealer or an affiliate of a registered broker-dealer. In no event shall any broker-dealer receive fees, commissions and markups which, in the aggregate, would exceed eight percent (8%).

We are required to pay certain fees and expenses incurred by us incident to the registration of the shares. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act, and the selling stockholders may be entitled to contribution. We may be indemnified by the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act that may arise from any written information furnished to us by the selling stockholders specifically for use in this prospectus, or we may be entitled to contribution.

The selling stockholders will be subject to the prospectus delivery requirements of the Securities Act including Rule 172 thereunder unless an exemption therefrom is available.

We agreed to cause the registration statement of which this prospectus is a part to remain effective until the date on which all of the shares registered hereby are either sold pursuant to the registration statement or sold or available for resale without restriction under Rule 144 under the Securities Act. The shares of common stock will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the shares of common stock covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the shares of common stock may not simultaneously engage in market making activities with respect to the shares of common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of common stock by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed them of the need to deliver a copy of this prospectus at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

There can be no assurance that any selling stockholder will sell any or all of the shares of common stock we registered on behalf of the selling stockholders pursuant to the registration statement of which this prospectus forms a part.

Once sold under the registration statement of which this prospectus forms a part, the shares of common stock will be freely tradable in the hands of persons other than our affiliates.

SELLING STOCKHOLDERS

We cannot advise you as to whether the selling stockholders will in fact sell any or all of such shares of common stock. In addition, the selling stockholders may have sold, transferred or otherwise disposed of, or may sell, transfer or otherwise dispose of, at any time and from time to time, the shares of our common stock in transactions exempt from the registration requirements of the Securities Act of 1933 after the date on which it provided the information set forth in the table below.

			Beneficial Ownership After this Offering (1)(2)	
Name	**Shares of Common Stock Owned Prior to this Offering**	**Shares of Common Stock Being Offered**	**Number of Shares**	**% (3)**
Abingworth Bioventures VII LP (4)	4,903,568	4,902,735	833	0.01%
Mario 2002 Grandchildren’s Trust (5)	608,921	326,847	282,074	0.09%
Mildred M. Mario Fifteen Year Residence Trust (6)	326,847	326,847	—	—
Jack W. Schuler Living Trust (7)	4,550,678	3,182,552	1,368,126	4.31%
JS Grandchildren Trust (8)	123,270	123,270	—	—
Schuler Descendants Trust (8)	123,270	123,270	—	—
Tino Hans Schuler Trust (8)	501,017	123,270	377,747	1.19%
Therese Heidi Schuler Trust (9)	501,017	123,270	377,747	1.19%
Tanya Eva Schuler Trust (9)	501,017	123,270	377,747	1.19%
Schuler Grandchildren LLC (9)	501,017	123,270	377,747	1.19%
Oracle Partners, L.P. (10)	2,615,481	892,295	1,723,186	5.22%
Oracle Ten Fund, L.P. (10)	855,243	297,431	557,812	1.73%
Oracle Institutional Partners, L.P. (10)	342,834	117,665	225,169	0.71%

(1) Assumes the sale of all shares of common stock registered pursuant to this prospectus, although the selling stockholder is under no obligation known to us to sell any shares of common stock at this time.
(2) Includes the 2018 PIPE Warrants within the ownership of each Selling Stockholder, although such warrants are not exercisable until May 19, 2019 by their terms.
(3) Based on 31,755,169 shares of common stock outstanding at March 14, 2019.
(4) Represents shares of common stock outstanding, issuable within 60 days of March 14, 2019, and upon the exercise of warrants: (a) 4,902,568 shares of common stock held by Abingworth Bioventures VII LP, consisting of (X) 4,699,272 shares of outstanding common stock and (Y) 233,463 shares of common stock issuable upon the exercise of warrants; and (b) 833 shares of common stock issuance upon exercise of an option held by Dr. Andrew Sinclair, a director of the Company. A Schedule 13G filed on December 27, 2018 reports voting and dispositive power over these shares.
(5) Represents shares of common stock outstanding, issuable within 60 days of March 14, 2019, and upon the exercise of warrants: 608,921 shares of common stock held by the Mario 2002 Grandchildren's Trust, consisting of (X) 593,357 shares of outstanding common stock and (Y) 15,564 shares of common stock issuable upon the exercise of warrants. The sons of Ernest Mario are the trustees of the Mario 2002 Grandchildren's Trust and may be deemed to beneficially own or otherwise exercise voting or dispositive powers with respect to the shares held directly by Mario 2002 Grandchildren's Trust.
(6) Represents shares of common stock outstanding, issuable within 60 days of March 14, 2019, and upon the exercise of warrants: 326,845 shares of common stock held by the Mildred M. Mario Fifteen Year Residence Trust, consisting of (X) 311,283 shares of outstanding common stock and (Y) 15,564 shares of common stock issuable upon the exercise of warrants. Mildred M. Mario is the trustee of the Mildred M. Mario Fifteen Year Residence Trust and may be deemed to beneficially own or otherwise exercise voting or dispositive powers with respect to the shares held directly by Mildred M. Mario Fifteen Year Residence Trust.
(7) Represents shares of common stock outstanding, issuable within 60 days of March 14, 2019, and upon the exercise of warrants: 4,550,678 shares of common stock held by the Jack W. Schuler Living Trust, consisting of (X) 3,274,568 shares of outstanding common stock and (Y) 1,276,110 shares of common stock issuable upon the exercise of warrants. Jack W. Schuler is the trustee of the Jack W. Schuler Living Trust and may be deemed to beneficially own or otherwise exercise voting or dispositive powers with respect to the shares held directly the Jack W. Schuler Living Trust.
(8) Represents shares of common stock outstanding, issuable within 60 days of March 14, 2019, and upon the exercise of warrants: (a) 123,270 shares of common stock held by the JS Grandchildren Trust, consisting of (X) 117,400 shares of outstanding common stock, and (Y) 5,870 shares of common stock issuable upon the exercise of warrants; (b) 123,270 shares of common stock held by the Schuler Descendants Trust, consisting of (X) 117,400 shares of outstanding common stock, and (Y) 5,870 shares of common stock issuable upon the exercise of warrants; and (c) 501,017shares of common stock held by the Tino Hans Schuler Trust, consisting of (X) 334,496 shares of outstanding common stock, and (Y) 166,521 shares of common stock issuable upon the exercise of warrants. Tino, Therese and Tanya Schuler are the trustees of the JS Grandchildren Trust, the Schuler Descendants Trust and the Tino Hans Schuler Trust and may be deemed to beneficially own or otherwise exercise voting or dispositive powers with respect to the shares held directly the JS Grandchildren Trust, the Schuler Descendants Trust and the Tino Hans Schuler Trust.
(9) Represents shares of common stock outstanding, issuable within 60 days of March 14, 2019, and upon the exercise of warrants: (a) 501,017shares of common stock held by the Therese Heidi Schuler Trust, consisting of (X) 334,496 shares of outstanding common stock and (Y) 166,521 shares of common stock issuable upon the exercise of warrants; (b) 501,017shares of common stock held by the Tanya Eva Schuler Trust, consisting of (X) 334,496 shares of outstanding common stock and (Y) 166,521 shares of common stock issuable upon the exercise of warrants; and (c) 501,017shares of common stock held by the Schuler Grandchildren LLC, consisting of (X) 334,496 shares of outstanding common stock and (Y) 166,521 shares of common stock issuable upon the exercise of warrants. George Schuler is the trustee or manager of the Therese Heidi Schuler Trust, the Tanya Eva Schuler Trust and Schuler Grandchildren LLC and may be deemed to beneficially own or otherwise exercise voting or dispositive powers with respect to the shares held directly the Therese Heidi Schuler Trust, the Tanya Eva Schuler Trust and Schuler Grandchildren LLC.
(10) Represents shares of common stock outstanding, issuable within 60 days of March 14, 2019, upon the exercise of options or warrants: (a) 3,862,856 shares of common stock held by Oracle Partners LP, consisting of (X) 1,368,106 shares of outstanding common stock, and (Y) 1,247,375 shares of common stock issuable upon the exercise of warrants; (b) 855,243 shares of common stock held by Oracle Ten Fund, LP, consisting of (X) 439,452 shares of outstanding common stock, and (Y) 415,791 shares of common stock issuable upon the exercise of warrants; and (c) 342,834 shares of common stock held by Oracle Institutional Partners LP, consisting of (X) 176,580 shares of outstanding common stock, and (Y) 160,651 shares of common stock issuable upon the exercise of warrants (assuming an exercise date of March 14, 2019). A Schedule 13G filed December 26, 2017 reports voting and dispositive power over these shares.

INDEX TO SOLENO THERAPEUTICS, INC. 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, 2018 and 2017, the related consolidated statements of operations, stockholders’ equity, and cash flows for each of the two years in the period ended December 31, 2018, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

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 19, 2019

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

	December 31, 2018	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 23,099	$ 17,100
Restricted cash	—	35
Prepaid expenses and other current assets	529	343
Due from related party	64	—
Minority interest investment in former subsidiary	978	—
Current assets held for sale	—	516
Total current assets	24,670	17,994
Long-term assets		
Property and equipment, net	12	23
Other assets	—	126
Intangible assets, net	18,469	20,413
Long-term assets held for sale	—	466
Total assets	$ 43,151	$ 39,022
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 934	$ 633
Accrued compensation and other current liabilities	943	973
Current liabilities held for sale	—	127
Total current liabilities	1,877	1,733
Long-term liabilities		
Series A warrant liability	49	70
Series C warrant liability	—	6
2017 PIPE Warrant liability	4,563	5,076
2018 PIPE Warrant liability	600	—
Contingent liability for Essentialis purchase price	5,649	5,082
Other liabilities	—	13
Long-term liabilities held for sale	—	225
Total liabilities	12,738	12,205
Commitments and contingencies (Note 7)		
Stockholders' equity		
Preferred Stock, $.001 par value, 10,000,000 shares authorized:		
Series B convertible preferred stock, 13,780 shares designated at December 31, 2018 and December 31, 2017; zero and 4,571 shares issued and outstanding at December 31, 2018 and at December 31, 2017, respectively. Liquidation value of zero.	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized,31,755,169 and 19,238,972 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively.	32	19
Additional paid-in-capital	157,413	140,495
Accumulated deficit	(127,032)	(113,697)
Total stockholders' equity	30,413	26,817
Total liabilities and stockholders' equity	$ 43,151	$ 39,022

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, 2018	2017
Operating expenses		
Research and development	$ 7,178	$ 3,069
Sales and marketing	—	26
General and administrative	6,556	6,584
Change in fair value of contingent consideration	567	2,492
Total operating expenses	14,301	12,171
Operating loss	(14,301)	(12,171)
Other income (expense)		
Cease-use income	6	4
Change in fair value of warrants liabilities	522	(685)
Gain on deconsolidation of former subsidiary	1,994	—
Interest and other expense, net	(62)	(590)
Total other income (expense)	2,460	(1,271)
Loss from continuing operations before provision for income tax benefit	(11,841)	(13,442)
Provision for income tax benefit from continuing operations	—	1,650
Loss from continuing operations	(11,841)	(11,792)
Loss from discontinued operations:		
Operating loss	(1,494)	(3,399)
Other expense	—	(194)
Total	(1,494)	(3,593)
Net loss	$ (13,335)	$ (15,385)
Loss per common share from continuing operations, basic and diluted	$ (0.56)	$ (1.31)
Loss per common share from discontinued operations, basic and diluted	(0.07)	(0.40)
Net loss per common share, basic and diluted	$ (0.64)	$ (1.71)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	20,975,479	8,977,795

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	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balances at January 1, 2017	12,780	$ —	3,357,387	$ 3	$ 101,744	$ (98,312)	$ 3,435
Stock-based compensation					1,000		1,000
Issuance of common stock on conversion of series B convertible preferred shares	(8,209)	(—)	1,641,800	2	(2)		—
Issuance of common stock to board members in lieu of cash payments for quarterly board fees			90,306	—	278		278
Issuance of common stock to acquire Essentialis			3,783,388	4	17,243		17,247
Sale of shares under the 2017 Aspire Purchase Agreement			2,083,333	2	9,998		10,000
Issuance of shares to Aspire Capital in lieu of commitment fees			141,666	—	602		602
Rounding adjustment resulting from 1 for 5 reverse split			(24)	—	—		—
Sale of shares to investors in the 2017 PIPE, net of costs of $1,172			8,141,116	8	13,819		13,827
Fair value at transaction date of warrants to purchase common stock under the 2017 PIPE					(4,187)		(4,187)
Net loss						(15,385)	(15,385)
Balances at December 31, 2017	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 common stock for bonuses			99,217	—	159		159
Issuance of common stock to board members in lieu of cash payments for quarterly board fees			146,371	—	275		275
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

See accompanying notes to consolidated financial statements

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

	For the Years Ended December 31,	
	2018	2017
Cash flows from operating activities:		
Net loss	$ (13,335)	$ (15,385)
Loss from discontinued operations	(1,494)	(3,593)
Loss from continuing operations	(11,841)	(11,792)
Adjustments to reconcile net loss from continuing operations to net cash used in operating activities:		
Depreciation and amortization	1,963	1,611
Stock-based compensation expense	988	880
Income tax benefit	—	(1,651)
Board fees paid with common stock	275	278
Change in fair value of stock warrants	(522)	685
Change in fair value of contingent consideration	567	2,492
Non-cash expense of issuing shares to Aspire Capital	—	602
Gain on deconsolidation of former subsidiary	(1,994)	—
Operating loss of minority interest investment	160	—
Change in operating assets and liabilities:		
Prepaid expenses, other current assets and other assets	(60)	(97)
Due from related party	(64)	—
Accounts payable	249	191
Accrued compensation and other current liabilities	(43)	(78)
Other long-term liabilities	—	(40)
Net cash used in continuing operating activities	(10,322)	(6,919)
Net cash used in discontinued operating activities	(1,361)	(3,031)
Net cash used in operating activities	(11,683)	(9,950)
Cash flows from investing activities:		
Costs of Essentialis acquisition paid	—	(573)
Security deposit on sublease	—	13
Purchases of property and equipment	(8)	(2)
Net cash used in continuing investing activities	(8)	(562)
Net cash (used in) provided by discontinued investing activities	(172)	716
Net cash (used in) provided by investing activities	(180)	154
Cash flows from financing activities:		
Proceeds from issuance of common stock	—	10,000
Proceeds from sale of common stock and common stock warrants	16,500	15,008
Cash paid for the issuance of common stock and common stock warrants	(198)	(1,063)
Net cash provided by continuing financing activities	16,302	23,945
Net cash provided by discontinued financing activities	1,525	225
Net cash provided by financing activities	17,827	24,170
Net increase in cash, cash equivalents and restricted cash from continuing operations	5,972	16,464
Net decrease in cash, cash equivalents and restricted cash from discontinued operations	(8)	(2,090)
Net increase in cash, cash equivalents and restricted cash	5,964	14,374
Net increase in cash and cash equivalents included in current assets held for sale	—	—
Cash, cash equivalents and restricted cash, beginning of period	17,135	2,761
Cash, cash equivalents and restricted cash, end of period	$ 23,099	$ 17,135
Supplemental disclosures of non-cash investing and financing information		
Issuance of common stock in Essentialis acquisition	$ —	$ 17,246
Contingent consideration of Essentialis acquisition	$ —	$ 2,590
Accrued liability for cost of issuing common stock	$ 52	$ —
Warrants issued in connection with sale of common stock	$ 582	$ 4,187

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 was initially established 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.

The Company’s previously wholly-owned subsidiary, NeoForce, Inc. or NFI, through which the Company acquired substantially all of the assets of an unrelated privately-held company, NeoForce Group, Inc., or NeoForce, also marketed innovative pulmonary resuscitation solutions for the inpatient and ambulatory neonatal markets.

The Company acquired Essentialis, Inc., or Essentialis, through a merger, or the Merger, on March 7, 2017, pursuant to Agreement and Plan of Merger dated December 22, 2016. 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 has tested Diazoxide Choline Controlled Release Tablet, or DCCR, as a treatment for Prader-Willi Syndrome, or 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. Consummation of the Merger was subject to various closing conditions, including the Company’s consummation of a financing of at least $8.0 million at, or substantially contemporaneous with, the closing of the Merger, which occurred on March 7, 2017 and the receipt of stockholder approval of the Merger at a special meeting of its stockholders, which was held on March 6, 2017.

Subsequent to the acquisition of Essentialis, the Company determined to divest, sell or otherwise dispose of the CoSense, NFI and Serenz businesses. Accordingly, and pursuant to ASC 205-20-45-10, any assets and liabilities related to the discontinued activities of CoSense, NFI and Serenz have been presented separately in the balance sheet as held for sale items, and the related operations reported herein for the CoSense, NFI and Serenz activities are reported as discontinued operations in the statements of operations.

The Company determined to divest, sell or otherwise dispose of the CoSense, NFI and Serenz businesses in order to focus on the development and commercialization of novel therapeutics for the treatment of rare diseases. The Company’s current research and development efforts are primarily focused on advancing its lead candidate, DCCR tablets for the treatment of PWS, into late-stage clinical development.

The Company sold its entire interest in NFI in a stock transaction that was completed on July 18, 2017, pursuant to a Stock Purchase Agreement dated July 18, 2017, or the NFI Purchase Agreement, entered into with Neoforce Holdings, Inc., a wholly-owned subsidiary of Flexicare Medical Limited, a privately-held United Kingdom company, for $720,000 and adjustments for inventory and the current cash balances held at NFI.

On December 4, 2017, Soleno, and Capnia, Inc., a Delaware corporation, or Capnia, entered into a joint venture with OptAsia Healthcare Limited, or OAHL. The purpose of the joint venture is to develop and commercialize medical monitors, including CoSense, that measure end-tidal carbon monoxide in breath to assist in the detection of excessive hemolysis in neonates, a condition in which red blood cells degrade rapidly and which can lead to adverse neurological outcomes.

The Company continues to separately evaluate alternatives for its Serenz portfolio.

Restatement of prior periods

During the preparation of the condensed consolidated financial statements as of September 30, 2018 and for the related three and nine months then ended, the Company determined that an error had been made in certain previously reported consolidated balance sheets and statements of operations for the valuation and resultant reporting of fair value for the Company’s Series A Warrants, resulting in the value of the warrant liability being overstated. The Company adjusted the prior period information reported in the September 30, 2018 interim condensed consolidated financial statements. The Company determined that the error was not material to any of the previously reported periods in which the error occurred and has not amended any previously issued consolidated financial statements.

The following table (in thousands, except share and per share amounts) sets forth the effects of the restatement on affected items within the Company's previously reported consolidated balance sheets and statements of operations for the periods ended December 31, 2017, March 31, 2018, and June 30, 2018, had the adjustments been made in the corresponding quarters.

	As of December 31, 2017			As of March 31, 2018			As of June 30, 2018			As of June 30, 2018		
	As Previously Reported	Correction of error	As Restated	As Previously Reported	Correction of error	As Restated	As Previously Reported	Correction of error	As Restated	As Previously Reported	Correction of error	As Restated
Series A Warrant liability	$ 352	$ (282)	$ 70	$ 291	$ (233)	$ 58	$ 1,015	$ (812)	$ 203	$ 1,015	$ (812)	$ 203
Total liabilities	12,487	(282)	12,205	13,312	(233)	13,079	17,507	(812)	16,695	17,507	(812)	16,695
Accumulated deficit	(113,979)	282	(113,697)	(117,734)	233	(117,501)	(125,371)	812	(124,559)	(125,371)	812	(124,559)

	Year Ended December 31, 2017			Quarter Ended March 31, 2018			Quarter Ended June 30, 2018			Six Months Ended June 30, 2018		
	As Previously Reported	Correction of error	As Restated	As Previously Reported	Correction of error	As Restated	As Previously Reported	Correction of error	As Restated	As Previously Reported	Correction of error	As Restated
Change in fair value of warrant liabilities	(967)	282	(685)	212	(49)	163	(3,834)	579	(3,255)	(3,622)	530	(3,092)
Total other income (expense)	(1,553)	282	(1,271)	234	(49)	185	(3,801)	579	(3,222)	(3,567)	530	(3,037)
Pro Forma net loss per common share	$ (1.75)	$ (0.04)	$ (1.71)	$ (0.19)	$ —	$ (0.19)	$ (0.38)	$ 0.03	$ (0.35)	$ (0.57)	$ 0.03	$ (0.54)

Note 2. Going Concern and Management's Plans

The Company had a net loss of $13.3 million during 2018 and has an accumulated deficit of $127.0 million at December 31, 2018 resulting from having incurred losses since its inception. The Company had $22.8 million of working capital at December 31, 2018 and used $11.7 million of cash in its operating activities during 2018. The Company has financed its operations principally through issuances of equity securities.

The Company has continued to focus on expense control, including reducing its workforce, reducing outside consultants, reducing legal fees and implementing a policy providing for Board members to receive common stock in lieu of cash payments for Board service compensation.

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 common stock and a warrant to purchase 0.05 shares of 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 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 may 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, consisting of certain line items within the 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 that management believes is of high credit quality. Cash and cash equivalents deposited with these commercial banks exceeded the Federal Deposit Insurance Corporation insurable limit at December 31, 2018 and 2017. 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. Restricted cash was security of the Company credit card.

Accounts Receivable

Accounts receivable as of December 31, 2017 consist of balances due from customers in the normal course of business and are classified as Assets Held for Sale (See Note 9). The Company did not record an allowance for doubtful accounts as this balance was deemed fully collectible. There were no accounts receivable as of December 31, 2018.

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.

Inventory

Inventory consists of raw materials to be used in the assembly of the Company's products, work-in-progress and finished goods. Inventory is stated at the lower of cost or net realizable value under the first-in, first-out (FIFO) method. As of December 31, 2017, the Company's inventory included approximately $213,000 of raw materials, approximately $30,000 of work-in-progress, and approximately $177,000 of finished goods and was classified as Assets Held for Sale (See Note 9). There was no inventory balance as of December 31, 2018.

Patent

On May 11, 2010, the Company entered into an Asset Purchase Agreement with BioMedical Drug Development, Inc., or BDDI, pursuant to which BDDI agreed to sell certain technology to us and BDDI received and was entitled to receive, among other consideration, certain royalty payments related to the technology. In June 2015, the Company and BDDI amended the BDDI Asset Purchase Agreement, pursuant to which the Company committed to pay aggregate cash payments of $450,000 and issued 8,000 shares of common stock to an affiliate of BDDI. Under the original Asset Purchase Agreement dated June 11, 2010, the Company purchased a patent for Breath End Tidal Gas Monitor. The patent was issued on June 19, 2003 and expires on August 1, 2027. The Company capitalized the fair value of the patent purchased as an intangible asset on its consolidated balance sheet and amortized the fair value over the remaining useful life of the patent.

The BDDI patent is reported as an Intangible Asset and classified as Assets Held for Sale as of December 31, 2017. (See Note 9.)

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.

Business Combinations

For business combinations the Company utilizes the acquisition method of accounting in accordance with ASC Topic 805, *Business Combinations.* These standards require that the total cost of an acquisition be allocated to the tangible and intangible assets acquired and liabilities assumed based on their respective fair values at the date of acquisition. The allocation of the purchase price is dependent upon certain valuations and other studies. Acquisition costs are expensed as incurred.

The Company recognizes separately from goodwill the fair value of assets acquired and the liabilities assumed. Goodwill as of the acquisition date is measured as the excess of consideration transferred and the acquisition date fair values of the assets acquired, and liabilities assumed. While the Company uses its best estimates and assumptions as a part of the purchase price allocation process to accurately value assets acquired and liabilities assumed at the acquisition date, the Company's estimates are subject to refinement. As a result, during the measurement period, which may be up to one year from the acquisition date, the Company may retroactively record adjustments to the fair value of the assets acquired and liabilities assumed, with the corresponding offset to goodwill. Upon the conclusion of the measurement period or final determination of the fair value of assets acquired or liabilities assumed, whichever comes first, any subsequent adjustments are recorded to the Company's consolidated statements of operations.

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.

Certain property and equipment were classified as Assets Held for Sale as of December 31, 2017. (See Note 9.)

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 expects to divest of its investment within one year of the balance sheet date.

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.

Intangible Assets in the amount of approximately $447,000 consisting of the patent acquired in the BDDI acquisition were classified as Assets Held for Sale as of December 31, 2017. (See Note 9.)

Intangible assets consist of the following at December 31, 2018 (in thousands).

	Amount	Accumulated Amortization	Net Amount	Useful Lives (years)
Patents and merger costs	$ 22,003	$ (3,534)	$ 18,469	11
Total	$ 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
2019	$ 1,944
2020	1,944
2021	1,944
2022	1,944
2023	1,944
2024 and thereafter	8,749
Total	$ 18,469

Amortization expense for the years ended December 31, 2018 and 2017, was $1.9 million and $1.7 million, respectively.

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 A and 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 each series of 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 all series of 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 granted to employees and directors are measured at the date of grant based on the estimated fair value of the award. We estimate the grant date fair value, 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 we grant to employees 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 on the volatilities of common stock of 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 November 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or the ASU 2016-18, "*Statement of Cash Flows: Restricted Cash*", which requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents and amounts generally described as restricted cash or restricted cash equivalents. These standards are effective for financial statements issued for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The Company adopted these standards in the first quarter of 2018 utilizing the retrospective transition method. There was no material impact on the Company's consolidated financial statements resulting from the adoption of this guidance.

In May 2017, the FASB issued ASU 2017-09, "*Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting*", which clarifies which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The standard is effective beginning after December 15, 2017 and early adoption is permitted. The Company adopted the standard in the first quarter of 2018. The adoption did not have a material impact on the Company's consolidated financial position and results of operations.

In March 2018, the FASB issued ASU 2018-05, *"Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118"*, to add various SEC paragraphs pursuant to the issuance of SEC Staff Accounting Bulletin No. 118, or SAB 118, to ASC 740 "Income Taxes". SAB 118 was issued by the SEC in December 2017 to provide immediate guidance for accounting implications of U.S. tax reform under the "*Tax Cuts and Jobs Act*", or the Tax Act, which became effective for the Company on January 1, 2018. The Company has adopted ASU 2018-09, and adoption of this ASU has no significant impact on its consolidated financial statements.

Recently Issued Accounting Standards

In February 2016, the FASB issued ASU 2016-02: "*Leases (Topic 842)*". ASU 2016-02 provides new comprehensive lease accounting guidance that supersedes existing lease guidance. Upon adoption of ASU 2016-02, the Company will be required to recognize most leases on its balance sheet at the beginning of the earliest comparative period presented with a corresponding adjustment to stockholders' equity. ASU 2016-02 requires the Company to capitalize most current operating lease obligations as right-of-use assets with a corresponding liability based on the present value of future operating lease obligations. Criteria for distinguishing leases between finance and operating are substantially similar to criteria for distinguishing between capital leases and operating leases in existing lease guidance. Lease agreements that are 12 months or less are permitted to be excluded from the balance sheet. Topic 842 includes a number of optional practical expedients that the Company may elect to apply. Expanded disclosures with additional qualitative and quantitative information will also be required. The adoption will include updates as provided under ASU 2018-01, Leases (Topic 842): Land Easement Practical Expedient for Transition to Topic 842, ASU 2018-10, Codification Improvements to Topic 842, Leases and ASU 2018-20, Leases (Topic 842): Narrow-Scope Improvements for Lessors. Topic 842 is effective for public entities with fiscal years beginning after December 15, 2018 and for all other entities for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. As the Company is an emerging growth company 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, Topic 842 will be effective for the Company beginning in fiscal 2020, although early adoption is permitted. The Company is currently evaluating the potential impact of adoption of this standard on its consolidated financial statements and the additional transition method under ASU 2018-11, which allows the Company to recognize Topic 842's cumulative effect within retained earnings in the period of adoption.

In July 2017, the FASB issued ASU 2017-11, "*Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features; (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*", (ASU 2017-11). Part I of this update addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of future equity offerings. Current accounting guidance creates cost and complexity for entities that issue financial instruments (such as warrants and convertible instruments) with down round features that require fair value measurement of the entire instrument or conversion option. Part II of this update addresses the difficulty of navigating Topic 480, Distinguishing Liabilities from Equity, because of the existence of extensive pending content in the FASB Accounting Standards Codification. This pending content is the result of the indefinite deferral of accounting requirements about mandatorily redeemable financial instruments of certain nonpublic entities and certain mandatorily redeemable noncontrolling interests. The amendments in Part II of this update do not have an accounting effect. The amendments in Part I of ASU 2017-11 are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. For all other entities, the amendments in Part I are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. As the Company is an emerging growth company 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, this ASU 2017-11 will be effective for the Company beginning in fiscal 2020, although early adoption is permitted. The Company is currently assessing the potential impact of adopting ASU 2017-11 on its consolidated financial statements and related disclosures.

In February 2018, the FASB issued ASU 2018-02, *"Income Statement—Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income"*, or ASU 2018-02, which allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Act and requires certain disclosures about stranded tax effects. ASU 2018-02 is effective for the Company beginning in 2019, with early adoption permitted, and shall be applied either in the period of adoption or retrospectively to each period (or periods) in which the effect of the change in the corporate income tax rate in the Tax Act is recognized. The adoption of this ASU is not expected to have a material impact on the Company's consolidated financial statements.

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 will be fixed at the grant date, which may lower their cost and reduce volatility in the income statement. This ASU is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. As the Company is an emerging growth company 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, this ASU 2018-07 will be effective for the Company beginning in fiscal 2020. Early adoption is permitted, including in an interim period. The adoption of this ASU is not expected to have a material impact on the Company's consolidated financial statements.

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 Company has not yet evaluated the impact of adoption of this ASU on its consolidated financial statements disclosures.

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 be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule is effective on November 5, 2018. The Company plans to apply the new guidance to its consolidated financial statements during the first quarter of 2019.

In October 2018, the FASB issued ASU 2018-17, *"Consolidation: Targeted Improvements to Related Party Guidance for Variable Interest Entities*", which modifies the guidance related to indirect interests held through related parties under common control for determining whether fees paid to decision makers and service providers are variable interest. This ASU is effective for public business entities for fiscal years beginning after December 15, 2019, including interim periods within that fiscal year. Early adoption is permitted. The adoption of this ASU is not expected to have a material impact on the Company's consolidated financial statements.

Note 4. Fair Value of Financial Instruments

The carrying value of the Company's cash, restricted 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, 2018			
	Total	**Level 1**	**Level 2**	**Level 3**
Liabilities				
Series A warrant liability	$ 49	$ 49	$ —	$ —
Series C warrant liability	—	—	—	—
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

	Fair Value Measurements at December 31, 2017			
	Total	**Level 1**	**Level 2**	**Level 3**
Liabilities				
Series A warrant liability	$ 70	$ 70	$ —	$ —
Series C warrant liability	6	—	—	6
2017 PIPE warrant liability	5,076	—	—	5,076
Essentialis purchase price contingency liability	5,082	—	—	5,082
Total common stock warrant and contingent consideration liability	$ 10,234	$ 70	$ —	$ 10,164

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 (see Note 8). 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 Warrant		Series C Warrant		2017 PIPE Warrants		2018 PIPE Warrants		Purchase Price
	Number of Warrants	Liability	Number of Warrants	Liability	Number of Warrants	Liability	Number of Warrants	Liability	Contingent Liability
Balance at January 1, 2018	485,121	$ 70	118,083	$ 6	6,024,425	$ 5,076	—	$ —	$ 5,082
Change in value of Series A Warrants	—	(21)	—	—	—	—	—	—	—
Change in value of Series C Warrants	—	—	—	(6)	—	—	—	—	—
Change in value of 2017 PIPE Warrants	—	—	—	—	—	(513)	—	—	—
Issuance of 2018 PIPE Warrants	—	—	—	—	—	—	513,617	582	—
Change in value of 2018 PIPE Warrants	—	—	—	—	—	—	—	18	—
Change in value of contingent liability	—	—	—	—	—	—	—	—	567
Balance at December 31, 2018	485,121	$ 49	118,083	$ —	6,024,425	$ 4,563	513,617	$ 600	$ 5,649

Note 5. Property and Equipment, Net

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

	December 31, 2018	December 31, 2017
Computer hardware	$ 67	$ 61
Computer software	2	—
Furniture and fixtures	23	23
Leasehold improvements	13	13
	105	97
Less accumulated depreciation and amortization	(93)	(74)
Total	$ 12	$ 23

Depreciation expense was approximately $19,000 and $44,000 for the years ended December 31, 2018 and December 31, 2017, respectively

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, with a term greater than one year, 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 has 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 are exercisable at any time 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 uses the closing price on the measurement date to determine the fair value of the Series A Warrants. The Series A Warrants contract further provide 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.

Since their issuance, a total of 4,800 Series A Warrants have been exercised. As of December 31, 2018, the fair value of the 485,121 outstanding Series A Warrants was approximately $49,000, and the decrease of approximately $21,000 in fair value during the year ended 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 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 provide 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.

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.

The Series C Warrants are exercisable into 118,083 shares of the Company's common stock. As of December 31, 2018, the fair value of the Series C Warrants was determined to be zero. The decline in the fair value of the liability for the Series C Warrants of approximately $6,000 during the year ended December 31, 2018 was recorded as other income (expense) in the consolidated statements of operations.

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, 2018	December 31, 2017
Volatility	90%	90%
Contractual term (years)	1.17	2.17
Expected dividend yield	—%	—%
Risk-free rate	2.60%	1.57%

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 holder to purchase one share 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, 2018, the fair value of the 2017 PIPE Warrants was estimated at $4.6 million. The decrease in the fair value of the liability for the 2017 PIPE Warrants of approximately $513,000 during the year ended December 31, 2018 was recorded as other income (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, 2018	December 31, 2017
Volatility	75%	67%
Contractual term (years)	0.8	0.8
Expected dividend yield	—%	—%
Risk-free rate	2.51%	1.76%

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 of each of the 10,272,375 units to purchase 0.05 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, 2018, the fair value of the 2018 PIPE Warrants was estimated at approximately $600,000. The approximate $18,000 increase in the fair value of the liability for the 2018 PIPE Warrants since they were issued was recorded as other income (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, 2018	December 19, 2018 (date of issue)
Volatility	75%	75%
Contractual term (years)	5.0	5.0
Expected dividend yield	—%	—%
Risk-free rate	2.51%	2.62%

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.
- *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. Commitments and Contingencies

Facility Leases

On July 1, 2015 the Company executed a new four-year non-cancelable operating lease agreement for 8,171 square feet of office space for its headquarters facility. The lease agreement provides for monthly lease payments of approximately $23,000 beginning in September 2015, with increases in the following three years. An additional 5,265 square feet of office space became part of the new lease agreement on March 1, 2016, and in December 2017 the Company subleased this additional space to a third party through the end of the lease term. The lease and the sublease both expire in August 2019.

The Company also leased office space under a non-cancelable operating lease agreement that was set to expire in May 2015, and in February 2015 the Company signed an amendment to its lease agreement, extending the lease through June 2018. The amendment provided for monthly lease payments of approximately $22,000 beginning in June 2015, with increases in the following two years. The Company subleased this facility in January 2016.

Minimum rental commitments under all noncancelable leases with an initial term in excess of one year as of December 31, 2018 were approximately $344,000 during 2019 and none thereafter, not including the impact of sublease payments the Company will receive under its existing sublease.

Rent expense was approximately $323,000 and $514,000 during the years ended December 31, 2018 and 2017, respectively.

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 8. Acquisition of Essentialis Inc.

On March 7, 2017, the Company acquired Essentialis through the merger of the Company’s wholly-owned subsidiary Company E Merger Sub, Inc., a Delaware corporation (“Merger Sub”), whereby Merger Sub merged into Essentialis, with Essentialis surviving the merger as a wholly owned subsidiary of the Company.

The transaction was accounted for as an asset acquisition under the acquisition method of accounting. The amendments in ASU 2017-01 provide a screen to determine when a set of assets and activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set of assets and activities is not a business.

In consideration, the Company issued 3,783,388 shares of common stock to stockholders of Essentialis on March 7, 2017. 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.

Since the acquisition was determined to be an asset acquisition, the total value of the purchase consideration was allocated to the asset acquired. The fair value of the shares issued on the completion of the merger and of the contingent shares to be issued in the future was based on the stock price of the Company on the date of completion of the merger. In addition, the trading history of the Company was reviewed to assess the reliability of the implied consideration value. The Company trades on the NASDAQ, a major U.S. stock exchange, and has significant average daily trading volume with tight intraday bid-ask spreads. These characteristics indicate Soleno’s shares are actively traded and provide a reliable indication of value. On March 7, 2017, the date of the transaction close, the Company’s stock was trading at $3.85 per common share. Additionally, the average closing price of the stock in the 30 calendar days leading up to the close was also approximately $3.85. Accordingly, the fair value of the shares issued on March 7, 2017 and the estimated fair value of the contingent shares to be issued in the future are based on this stock price.

The agreement to pay cash upon the achievement of the commercial milestones results in the recognition of a contingent consideration. The fair value of the contingent cash consideration is based on the Company’s 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. In determining the likelihood of this occurring, the analysis relied on 2016 research published by BIO, Biomedtraker, & Amplion titles “Clinical Development Success Rates 2006-2015.” Based on management’s assessment, a 56% probability of achieving each milestone was determined to be reasonable. Additionally, the Company anticipated at the time of the merger that it could reach the commercial milestones of $100.0 million and $200.0 million in applicable revenue in 2023 and 2025, respectively.

The Company recorded the acquisition pursuant to the guidance in ASC 805, which provides that not all of the relevant information needed to complete acquisition-date measurements may be obtainable or known at the time of closing the acquisition and in time for issuance of interim or annual financial statements. Therefore, ASC 805 provides for a “measurement period” during which adjustments to the provisional valuation amounts initially recorded can be made in order to reflect information, existing at the acquisition date, but of which management subsequently obtains or becomes aware. ASC 805 provides that the measurement period can extend for up to, but not exceed, one year.

Management engaged independent professional assistance and advice in order to assess the fair value of the contingent stock and cash consideration as of March 7 and December 31, 2017. During the process of determining the fair value of the contingent consideration at December 31, 2017, the Company became aware that certain of the subjective assumptions made at the time of the initial valuation should be modified based upon management’s increased understanding of the commercial capabilities of the DCCR drug of which it became aware subsequent to the acquisition. Accordingly, the Company determined that it was appropriate to adjust the provisional valuation amounts recorded for the contingent stock and cash consideration made at the inception in March 2017. As a result, the value of the contingent cash consideration to be paid upon completing successive sales milestones increased and the value of the contingent stock consideration payable upon timing milestones was reduced; the resulting combined change to the total contingent consideration was not material. The initial valuation of the contingent consideration determined the fair value of the contingent stock consideration to be $4.2 million and the fair value of the contingent cash consideration to be $1.1 million, for the combined value of $5.3 million for the total of the stock and cash contingent consideration. The revision of the initial valuation of the contingent consideration, made within the measurement period, determined the fair value of the contingent stock consideration to be $2.7 million and the fair value of the contingent cash consideration to be $2.6 million, for the combined value of $5.3 million for the total of the contingent stock and cash consideration.

Also subsequent to March 7, 2017 and prior to reporting the balance sheet and results of operations as of December 31, 2017, and for the year then ended, the Company completed its assessment of the tax effect on the net assets acquired by obtaining the independent study and report regarding the change in control in the previously outstanding stock of Essentialis. As a result of completing the study, the Company determined that, pursuant to Section 382 of the Internal Revenue Code, the utilization of Essentialis's federal and state operating loss carryforwards were limited, which required the Company to record a net deferred tax liability in the amount of $1.7 million, deferred to future periods, as an element of the assets acquired. As a consequence of recording the net deferred tax liability, the Company's valuation allowance was reduced by $1.7 million, which resulted in the provision for income tax benefit and an increase in the value of the intangible asset acquired.

The probability weighted milestone payments were discounted to determine the present value of future cash payments. The analysis utilized the weighted average cost of capital (WACC) discount rate. The WACC used for the first and second milestones were 30% and 21%, respectively.

The aggregate purchase price consideration was as follows (in thousands).

Fair value of stock consideration	$	17,246
Fair value of contingent consideration		2,590
Total purchase price consideration	$	19,836

The fair value of the asset acquired is as follows (in thousands).

Patents	$	19,836
Net assets acquired	$	19,836

As an asset acquisition, the Company also capitalized approximately $573,000 of total costs incurred to complete the acquisition consisting of legal fees of approximately $469,000, printing fees of approximately $75,000 and accounting and other fees of approximately $29,000. Additionally, the Company recorded as part of the purchase price consideration the value equivalent to the deferred tax liability that resulted from acquiring the assets in the amount of $1.7 million. The total intangible asset of $22.0 million was recorded on the balance sheet and is being amortized ratably over the life of the patents through June 30, 2028.

The acquisition of Essentialis assets was completed in March 2017 and the purchase price was established at the date of closing based upon consideration paid at closing and an estimate of the future contingent consideration to be paid. Subsequent to the acquisition date and prior to reporting the balance sheet and results of operations as of December 31, 2017, and for the year then ended, the Company completed and finalized its assessments of the fair value of consideration paid and of the tax effect on the net assets acquired resulting from the change in control in the previously outstanding stock of Essentialis. As a result of completing the study of the fair value of the consideration paid, the Company revised the initial estimate of the fair value paid at closing and of the future contingent consideration to be paid; accordingly, the initial purchase cost of the asset acquired was adjusted as of March 2017 and the change in amortization of the related intangible asset was recorded in the fourth quarter of 2017. As a result of completing the study of the tax effect, the Company determined that, pursuant to Section 382 of the Internal Revenue Code, the utilization of Essentialis's operating loss carryforwards were limited, which required the Company to record a tax liability in the amount of $1.6 million, deferred to future periods, for the assets acquired for which the cost was recorded as an element of the of assets required. Accordingly, the initial purchase cost of the asset acquired was adjusted as of March 2017 and the increase in amortization of the related intangible asset was recorded in the fourth quarter of 2017.

The fair value of the liability for the contingent consideration payable by the Company achieving the commercial sales milestones of $100.0 million and $200.0 million was initially established as $2.6 million at the time of the merger. The fair value of the contingent consideration payable increased to $5.1 million at December 31, 2017 and to $5.6 million at December 31, 2018, based on the Company's assessment that it could reach the commercial sales milestones of in 2024 and 2026, respectively. The changes in fair value of the contingent consideration payable after the time of the merger are recognized as income or expense in the line titled Change in fair value of contingent consideration in the Company's consolidated statements of operations.

Note 9. Discontinued Operations and Assets Held for Sale

(i) Assets held for sale and discontinued operations

Subsequent to the merger with Essentialis described above, the Company explored opportunities divest, sell or dispose of the CoSense, Neo Force, Inc. and Serenz businesses.

Under ASC 205-20-45-10, during the period in which a component meets the assets held for sale and discontinued operations criteria, an entity must present the assets and liabilities of the discontinued operation separately in the asset and liability sections of the balance sheet for the comparative reporting periods. The prior period balance sheet should be reclassified for the held for sale items. For income statements, the current and prior periods should report the results of operations of the component in discontinued operations when comparative income statements are presented.

The components of the Consolidated Balance Sheet accounts presented as assets and liabilities held for sale as of December 31, 2017 follow (in thousands). There were no assets or liabilities held for sale as of December 31, 2018 after the deconsolidation of Capnia.

	December 31, 2017
Current assets	
Accounts receivable	$ 50
Inventory	420
Prepaid expenses and other current assets	46
Total current assets held for sale	$ 516
Long-term assets	
Property and equipment, net	$ 20
Other intangible assets	446
Total long-term assets held for sale	$ 466
Current liabilities	
Accounts payable	$ 51
Accrued compensation and other current liabilities	76
Total current liabilities for sale	$ 127
Long-term liabilities	
Other long-term liabilities	$ 225
Total long-term liabilities held for sale	$ 225

The components of the Consolidated Statements of Operations presented as discontinued operations follow (in thousands).

	Year Ended December 31,	
	2018	2017
Product revenue	$ 62	$ 735
Cost of product revenue	32	820
Gross profit (loss)	30	(85)
Expenses		
Research and development	1,106	2,427
Sales and marketing	25	218
General and administrative	393	669
Total expenses	1,524	3,314
Operating loss	(1,494)	(3,399)
Other expense		
Loss on sale of assets	—	(186)
Other expense	—	(8)
Total other expense	—	(194)
Net loss from discontinued operations	$ (1,494)	$ (3,593)

Stock-based compensation expense of approximately $76,000 and $120,000 was classified in discontinued operations for the years ended December 31, 2018 and 2017, respectively.

(ii) NFI Sale

On September 2, 2015, the Company established NeoForce, Inc. (“NFI”), a wholly owned subsidiary of the Company and through NFI, acquired substantially all of the assets of an unrelated privately held company NeoForce Group, Inc.(“NeoForce”).

On July 18, 2017, the Company completed the sale of stock of its 100% wholly-owned subsidiary, NFI, primarily related to the Company's portfolio of neonatology resuscitation business pursuant to a Stock Purchase Agreement (the "Purchase Agreement"), dated as of July 18, 2017, with NeoForce Holdings, Inc. ("Holdings"), a 100% owned subsidiary of Flexicare Medical Limited, a privately held United Kingdom company, for $720,000 and adjustments for inventory and the current cash balances held at NFI. The Company also received the total outstanding accounts receivable and inventory held by NFI at the date of sale, as it was collected or sold, respectively. The transactions contemplated by the Purchase Agreement are a continuation of a process previously disclosed by the Company of evaluating strategic alternatives and focusing on the Company's rare disease therapeutic business. The Purchase Agreement includes customary terms and conditions, including an adjustment to the purchase price based on inventory and accounts receivables, and provisions that require the Company to indemnify Holdings, to the maximum of $250,000, for certain losses that it incurs as a result of a breach by the Company of its representations and warranties in the Purchase Agreement and certain other matters, which indemnification obligation terminates once the statute of limitations expires. Proceeds from the sale are payable to the Company as follows: (1) a $720,000 payment to the Company in cash on July 18, 2017, (2) the value of outstanding accounts receivable as it is collected by NFI following July 18, 2017, payable on a monthly basis, and (3) the value of inventory as it is sold following July 18, 2017, payable on a monthly basis. The Purchase Agreement contains customary representations and warranties of each of the parties.

(iii) CoSense Joint Venture Agreement

In December 2017, the Company entered into a joint venture with OAHL with respect to its CoSense product by agreeing to sell shares of Capnia, its 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. CoSense measures CO, which can be elevated due to endogenous causes such as excessive breakdown of red blood cells, or hemolysis, or exogenous causes such as CO poisoning and smoke inhalation. The first target market for CoSense is for the use of ETCO measurements to aid in detection of hemolysis in neonates, a disorder in which CO and bilirubin are produced in excess as byproducts of the breakdown of red blood cells. The Company's entry into the joint venture results 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 will invest up to a total of $2.2 million in Capnia's common shares on an incremental quarterly basis commencing in December 2017. Going forward, OAHL will be responsible for funding a portion of the Capnia operations. The Joint Venture Agreement provided that Capnia would issue shares of common shares 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 have 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 holds a controlling interest in Capnia and resulted in the deconsolidation of Capnia's financial statements with 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 relates 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 is included in other income from continuing operations on the Company's consolidated statements of operations. The remaining 47% investment in Capnia is classified as an equity method investment and presented as a Minority interest investment in former subsidiary in the consolidated balance sheet.

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, 2018, 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 December 22, 2016, the Company entered into the Merger Agreement with Essentialis. Consummation of the Merger was subject to various closing conditions, including the Company's consummation of a financing of at least $8.0 million at, or substantially contemporaneous with, the closing of the Merger, which occurred on March 7, 2017 and the receipt of stockholder approval of the Merger at a special meeting of stockholders, which the Company received on March 6, 2017.

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 11, 2017, the Company entered into a Securities Purchase Agreement with certain purchasers, pursuant to which the Company 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 the Company's common stock and a warrant to purchase 0.74 shares of the Company's 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. 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 2017 Resale Shares. The registration statement was declared effective in February 2018.

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 agreed to prepare and file with the SEC a registration statement to register for resale the 2018 Resale Shares prior to March 31, 2019.

Equity Incentive Plans

The Company has adopted the 1999 Incentive Stock Plan, the 2010 Equity Incentive Plan, and the 2014 Equity Incentive Plan, or the 2014 Plan, and together, the Plans. The 1999 Incentive Stock Plan expired in 2009, and the 2010 Equity Incentive Plan has been closed to new issuances. 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, 2018, a total of 1,150,961 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, 2018 and 2017 of approximately $988,000 and $1.0 million, respectively, of which approximately $76,000 and $120,000 and was recorded in discontinued operations in 2018 and 2017, respectively. 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, 2018 and December 31, 2017.

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

	Year ended	
	December 31, 2018	December 31, 2017
Research and development	$ 205	$ 93
General and administrative	707	787
Total	$ 912	$ 880

Stock Options

The Company granted options to purchase 756,086 and 622,755 of the Company's common stock in 2018 and 2017, 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, 2018	December 31, 2017
Expected life (years)	5.5-6.0	5.5-6.1
Risk-free interest rate	2.7%-2.8%	1.9%-2.2%
Volatility	70%-71%	61%-69%
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 common stock of 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 transactions for the years ended December 31, 2018 and 2017 as issued under the Plans.

	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, 2017	191,770	581,687	$ 17.10	8.48
Additional shares authorized	134,295			
Amendment to plan to authorize additional shares	1,785,837			
Options granted	(622,755)	622,755	$ 3.04	
Options exercised	—	—	—	—
Options canceled/forfeited	177,455	(177,455)	$ 8.84	—
Balance at December 31, 2017	1,666,602	1,026,987	$ 9.99	7.94
Additional shares authorized	223,742			
Shares allocated to grants of restricted stock units	(99,217)			
Options granted	(756,086)	756,086	$ 1.68	
Options exercised	—	—	—	—
Options canceled/forfeited	115,920	(115,920)	$ 12.72	—
Balance at December 31, 2018	1,150,961	1,667,153	$ 6.03	8.27
Options vested at December 31, 2018		820,422	$ 9.85	7.64
Options vested and expected to vest at December 31, 2018		1,667,153	$ 6.03	8.27

The weighted-average grant date fair value of employee options granted was $1.08 and $1.88 per share for the year ended December 31, 2018 and December 31, 2017, respectively. At December 31, 2018 total unrecognized employee stock-based compensation was $1.2 million, which is expected to be recognized over the weighted-average remaining vesting period of 2.5 years. As of December 31, 2018, the outstanding stock options had an intrinsic value of approximately $71,000.

The fair value of an equity award granted to a nonemployee generally is determined in the same manner as an equity award granted to an employee. In most cases, the fair value of the equity securities granted is more reliably determinable than the fair value of the goods or services received. Stock-based compensation related to its grant of options to non-employees has not been material to date.

Restricted Stock Units

There were 99,217 restricted stock units granted by the Company during the year ended December 31, 2018 to employees and nonemployees. 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 $159,000 of the related stock-based compensation expense recognized at that time.

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, 2018, 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, 2018, 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 1,851 common stock warrants issued in 2009, with an exercise price of $108.00 and a term of 10 years, which expired in January 2019 and 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,	
	2018	2017
United States	$ (11,830)	$ (13,707)
Foreign	(11)	(17)
Income (loss) before income taxes	$ (11,841)	$ (13,724)
Income (loss) resulting from discontinued operations	$ (1,494)	$ (3,593)
Taxes allocated to discontinued operations	—	—

The components of the provision for income tax benefit follows (in thousands).

	December 31,	
	2018	2017
Current:		
Federal	$ —	$ —
State	—	1
Foreign	—	—
	—	1
Deferred		
Federal	—	(1,578)
State	—	(73)
Foreign	—	—
	—	(1,651)
Total provision for income taxes benefit	$ —	$ (1,650)

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,	
	2018	2017
Tax on the loss before income tax expense computed at the federal statutory rate	$ (2,486)	$ (4,666)
State tax (benefit) at statutory rate, net of federal benefit	(187)	(67)
Tax reform	—	10,613
Foreign rate differential	2	3
Change in valuation allowance	4,143	(8,485)
Change in research and development credits	(99)	(121)
Stock based compensation—ISOs	143	295
Change in fair value of warrants	(110)	343
Change in fair value of contingent consideration	119	—
Gain on deconsolidation	(4)	—
Disallowance of loss on discontinued operations	(426)	—
Acquisition costs	—	203
Change in NOL true up	(590)	—
Change in temporary difference true up	(456)	—
Loss on sale of NFI	—	(677)
Other	(49)	909
Provision for income tax benefit	$ —	$ (1,650)

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, 2018 and 2017 (in thousands).

	December 31, 2018	December 31, 2017
Non-Current Deferred Tax Assets:		
Federal and state net operating loss carryforwards	$ 28,532	$ 25,486
Research and other credits	2,037	1,807
Reserves and accruals	52	145
Assets held for sale	15	17
Fixed assets	67	—
Capital loss carryover	425	459
Stock based compensation	70	36
Other deferred tax assets	542	—
Gross non-current deferred tax assets	31,740	27,950
Intangible Assets	(4,062)	(4,414)
Fixed Assets	—	(3)
Total non-current deferred tax liabilities	(4,062)	(4,417)
Total deferred tax assets	27,678	23,533
Valuation allowance	(27,678)	(23,533)
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 $4.1 million from December 31, 2017 to December 31, 2018 primarily due to the generation of current year net operating losses and research and development credits claimed.

As of December 31, 2018, the Company had $129.8 million of federal, $51.4 million of state and approximately $264,000 of foreign net operating losses available to offset future taxable income. The federal net operating loss carryforwards begins to expire in 2019, 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. As of December 31, 2018, the Company also had $1.2 million of federal and approximately $798,000 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 is in process of completing an 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 and, as such, is not able at this time to determine the impact on the NOL carryforwards, if any, as of the date of these consolidated financial statements as result of the 2018 share issuances. Once the analysis is completed, the Company will make any appropriate adjustments to the balances of NOLs to be carried forward and thus adjust the NOL deferred tax asset accordingly, if required.

United States taxes and foreign withholding taxes have not been provided on undistributed earnings for certain non-United States subsidiaries as of December 31, 2018, 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, 2018	December 31, 2017
Beginning balance	$ 854	$ 795
Increases (decreases) related to prior year tax positions	23	(4)
Increase related to current year tax positions	87	63
Ending Balance	$ 964	$ 854

There were no unrecognized tax benefits that would impact the effective tax rate as of December 31, 2018 and December 31, 2017. As of December 31, 2018, unrecognized tax benefits of approximately $964,000 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.

In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118 (“SAB 118”), Income Tax Accounting Implications of the Tax Cuts and Jobs Act (SAB 118), which allowed us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. As a result, we previously provided provisional estimates of the effect of the Tax Act in our financial statements. In the fourth quarter of 2018, we completed our analysis to determine the effect of the Tax Act and determined that no further adjustments were needed.

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 2018, 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.

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 no material unrecognized assets or liabilities related to uncertain tax positions as of December 31, 2018. The Company does not anticipate any significant changes in such uncertainties and judgments during the next 12 months. 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.

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, 2018 and 2017, 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,	
	2018	2017
Convertible preferred stock	—	914,200
Warrants issued to 2010/2012 convertible note holders to purchase common stock	102,070	102,070
Options to purchase common stock	1,667,153	1,026,987
Warrants issued in 2009 to purchase common stock	1,851	1,851
Warrants issued to underwriter to purchase common stock	16,500	16,500
Series A warrants to purchase common stock	485,121	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	—
Total	9,514,982	9,275,399

Note 13. Compensation Plan for Board Members

In 2017, the Compensation Committee of the Board of Directors recommended, and the Board approved a revised compensation plan pursuant to which all board fees are paid in common stock of the Company. Payment to the Board of Directors in shares of the Company’s common stock is made after the close of the quarter in which the compensation is earned. During 2018 and 2017, the Company issued 146,371 and 90,306 shares, respectively, of common stock to its Board members for fees earned.

Note 14. 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. To date, the Company has not made any matching contributions.

Note 15. Subsequent Events

On February 4, 2019 the Company formed a new wholly owned subsidiary in Ireland named Soleno Therapeutics Europe Limited.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the estimated costs and expenses to be incurred in connection with the issuance and distribution of the securities registered under this Registration Statement. All amounts are estimates except the Securities and Exchange Commission registration fee.

	Amount to be Paid
SEC registration fee	$ 3,034
Legal fees and expenses	52,000
Accountant’s fees and expenses	17,000
Miscellaneous expenses	198,000
Total	$ 270,034

Item 14. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law, or the Delaware Law, provides that a corporation may indemnify directors and officers as well as other employees and individuals against expenses (including attorneys’ fees), judgments, fines and amounts paid in settlement in connection with specified actions, suits or proceedings, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation — a “derivative action”), if they acted in good faith and in a manner they reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe their conduct was unlawful. A similar standard is applicable in the case of derivative actions, except that indemnification only extends to expenses (including attorneys’ fees) incurred in connection with defense or settlement of such action, and the statute requires court approval before there can be any indemnification where the person seeking indemnification has been found liable to the corporation. Under Section 145 of the Delaware Law, a corporation shall indemnify an agent of the corporation for expenses actually and reasonably incurred if and to the extent such person was successful on the merits in a proceeding or in defense of any claim, issue or matter therein.

Section 145 of the Delaware Law authorizes a court to award, or a corporation’s board of directors to grant, indemnity to directors and officers in terms sufficiently broad to permit such indemnification under certain circumstances for liabilities (including reimbursement for expenses incurred) arising under the Securities Act of 1933, as amended. Our amended and restated certificate of incorporation and bylaws provide for indemnification of our directors, officers, employees and other agents to the maximum extent permitted by the Delaware Law. We have also entered into agreements with its directors and officers that will require us, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers to the fullest extent not prohibited by law. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers or persons controlling our company pursuant to such provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

There is no litigation pending or, to the best of our knowledge, threatened which might or could result in a claim for indemnification by a director or officer.

Item 15. Recent Sales of Unregistered Securities.

2018 PIPE Offering

On December 19, 2018, we entered into the Unit Purchase Agreement, with the selling stockholders pursuant to which we sold and issued 10,272,375 immediately separable units at a price per unit of $1.60625 for aggregate gross proceeds of approximately $16,500,000. Each unit consisted of one share of our common stock and a warrant to purchase 0.05 of a share of our common stock at an exercise price of $2.00 per share, for an aggregate of 10,272,375 Shares and corresponding warrants to purchase 513,617 Warrant Shares.

Item 16. Exhibits and Financial Statement Schedules.

The following exhibits are included as part of this Form S-1.

EXHIBIT INDEX

Exhibit Number	Description of Document	Registrant's Form	Incorporated by Reference from 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	
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	

Exhibit Number	Description of Document	Registrant's Form	Incorporated by Reference from Date Filed with the SEC	Exhibit Number	Filed Herewith
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	
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	

Exhibit Number	Description of Document	Incorporated by Reference from Registrant's Form	Date Filed with the SEC	Exhibit Number	Filed Herewith
5.1	Opinion of Wilson Sonsini Goodrich & Rosati, Professional Corporation.				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	June 10, 2014	10.1	
10.2	1999 Incentive Stock Plan and forms of agreements thereunder.	S-1	June 10, 2014	10.2	
10.3	2010 Equity Incentive Plan and forms of agreements thereunder.	S-1	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	
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	

Exhibit Number	Description of Document	Incorporated by Reference from Registrant's Form	Date Filed with the SEC	Exhibit Number	Filed Herewith
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	
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	

Exhibit Number	Description of Document	Registrant's Form	Incorporated by Reference from Date Filed with the SEC	Exhibit Number	Filed Herewith
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	
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	

Exhibit Number	Description of Document	Registrant's Form	Incorporated by Reference from Date Filed with the SEC	Exhibit Number	Filed Herewith
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	Emplooment Agreement with Kristen Yen				X
21.1	Subsidiaries				X
23.2	Consent of Marcum LLP				X
24.1	Power of Attorney (incorporated by reference to the signature page to this registration statement)				
101.INS	XBRL Instance Document.				X
101.SCH	XBRL Taxonomy Extension Schema Document.				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.				

Item 17. Undertakings.

1. The undersigned registrant hereby undertakes to file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933.

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

Provided, however, that paragraphs (B)(1)(i) and (B)(1)(ii) of this section do not apply if the registration statement is on Form S-3, Form S-8 or Form F-3, and the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the Registrant pursuant to Section 13 or Section 15(d) of the Exchange Act that are incorporated by reference in the registration statement.

2. The undersigned registrant hereby undertakes that, for the purpose of determining any liability under the Securities Act of 1933, as amended, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

3. The undersigned registrant hereby undertakes to remove from registration by means of a post-effective amendment any of the securities being registered that remain unsold at the termination of the offering.

4. The undersigned registrant hereby undertakes that, for the purposes of determining liability to any purchaser:

If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

5. Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, may be permitted to directors, officers and controlling persons of the undersigned registrant according the foregoing provisions, or otherwise, the undersigned registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933, as amended, and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Redwood City, State of California, on this 29th day of March, 2019.

SOLENO THERAPEUTICS, INC.

By: /s/ Anish Bhatnagar
Anish Bhatnagar
President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons 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 29, 2019
/s/ Jonathan Wolter Jonathan Wolter	Chief Financial Officer (Principal Financial and Accounting Officer)	March 29, 2019
/s/ Ernest Mario Ernest Mario	Chairman	March 29, 2019
/s/ Andrew Sinclair Andrew Sinclair	Director	March 29, 2019
/s/ William G. Harris William G. Harris	Director	March 29, 2019
/s/ Mahendra Shah Mahendra Shah	Director	March 29, 2019
/s/ Stuart Collinson Stuart Collinson	Director	March 29, 2019

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below, hereby constitutes and appoints Anish Bhatnagar and Jonathan Wolter his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to the registration statement, including post-effective amendments, and registration statements filed pursuant to Rule 462 under the Securities Act of 1933, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, and does hereby grant 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 requisite and necessary to be done in and about the foregoing, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons 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 29, 2019
/s/ Jonathan Wolter Jonathan Wolter	Chief Financial Officer (Principal Financial and Accounting Officer)	March 29, 2019
/s/ Ernest Mario Ernest Mario	Chairman	March 29, 2019
/s/ Andrew Sinclair Andrew Sinclair	Director	March 29, 2019
/s/ William G. Harris William G. Harris	Director	March 29, 2019
/s/ Mahendra Shah Mahendra Shah	Director	March 29, 2019
/s/ Stuart Collinson Stuart Collinson	Director	March 29, 2019

Exhibit 5.1

Wilson Sonsini Goodrich & Rosati
PROFESSIONAL CORPORATION

650 Page Mill Road
Palo Alto, CA 94304-1050
PHONE 650.493.9300
FAX 650.493.6811
www.wsgr.com

March 29, 2019

Soleno Therapeutics, Inc.
1235 Radio Road, Suite 110
Redwood City, CA 94065

Re: Registration Statement on Form S-1

Ladies and Gentlemen:

This opinion is furnished to you in connection with the Registration Statement on Form S-1 (the "Registration Statement"), filed by Soleno Therapeutics, Inc. (the "Company") with the Securities and Exchange Commission on even date herewith in connection with the registration under the Securities Act of 1933, as amended, of an aggregate of 10,785,992 shares of the Company's common stock (the "Common Stock"), which consists of 10,272,375 shares of Common Stock issued under the Securities Purchase Agreement dated December 19, 2018 (the "Agreement"), and up to 513,617 shares of Common Stock that may be purchased upon exercise of warrants (the "Warrants") issued under the Agreement.

We are acting as counsel for the Company in connection with the registration of Common Stock by the Company. In such capacity, we have examined the Agreement. We have also examined originals or copies, certified or otherwise identified to our satisfaction, of such documents, corporate records, certificates of public officials and other instruments as we have deemed necessary for the purposes of rendering this opinion. In our examination, we have assumed the genuineness of all signatures, the authenticity of all documents submitted to us as originals, the conformity with the originals of all documents submitted to us as copies, the authenticity of the originals of such documents and the legal competence of all signatories to such documents.

Based on the foregoing and in reliance thereon and subject to the assumptions, qualifications and limitations set forth herein, we are of the opinion that:

(i) the 10,272,375 shares of Common Stock are validly issued, fully paid and non-assessable; and

(ii) the 513,617 shares of Common Stock underlying the Warrants will, when issued by the Company in accordance with the Warrants, will be validly issued, fully paid and non-assessable.

We are members of the Bar of the State of California and this opinion is limited solely to the federal laws of the United States of America and the General Corporation Law of the State of Delaware (including the statutory provisions and all applicable judicial decisions interpreting those laws).

We consent to the use of this opinion as an exhibit to the Registration Statement, and we consent to the reference of our name under the caption "Legal Matters" in the prospectus forming part of the Registration Statement.

Very truly yours,

/s/ Wilson Sonsini Goodrich & Rosati

WILSON SONSINI GOODRICH & ROSATI
Professional Corporation

CAPNIA, INC.

EMPLOYMENT AGREEMENT

This Employment Agreement (the "**Agreement**") is entered into as of May 15, 2015, (the "**Effective Date**") by and between Capnia, Inc. (the "**Company**"), and Kristen Yen ("**Executive**").

1. Duties and Scope of Employment.

(a) Positions and Duties. This employment agreement between the Executive and the Company will commence on May 15, 2015 (the "**Start Date**"). Executive will serve as Vice President, Clinical & Regulatory Affairs of the Company. Executive will render such business and professional services in the performance of her duties, consistent with Executive's position within the Company, as will reasonably be assigned to her by the Company's Board of Directors (the "**Board**"). The Board may modify Executive's job title and duties as it deems necessary and appropriate in light of the Company's needs and interests from time to time. The period of Executive's employment under this Agreement is referred to herein as the "**Employment Term**."

(b) Obligations. During the Employment Term, Executive will perform her duties faithfully and to the best of her ability and will devote substantially all of her business efforts and time to the Company. For the duration of the Employment Term, Executive agrees not to actively engage in any other employment, occupation or consulting activity for any direct or indirect remuneration that would impact in any material respect her ability to perform her duties and obligations hereunder.

2. At-Will Employment. The parties agree that Executive's employment with the Company will be "at-will" employment and may be terminated at any time with or without Cause or notice. Executive understands and agrees that neither her job performance nor promotions, commendations, bonuses or the like from the Company give rise to or in any way serve as the basis for modification, amendment, or extension, by implication or otherwise, of her employment with the Company. However, as described in this Agreement, Executive may be entitled to severance benefits depending on the circumstances of Executive's termination of employment with the Company.

3. Term of Agreement. This Agreement will have an initial term running from the Effective Date through the first anniversary of the Start Date (the "**Initial Term**"). On the first anniversary of the Start Date, this Agreement will renew automatically for additional one (1) year terms (each an "**Additional Term**"), unless either party provides the other party with written notice of non-renewal at least thirty (30) days prior to the date of automatic renewal. If Executive becomes entitled to benefits under Section 8 during the term of this Agreement, the Agreement will not terminate until all of the obligations of the parties hereto with respect to this Agreement have been satisfied.

4. Compensation.

(a) Base Salary. During the Employment Term, the Company will pay Executive an annual salary of $215,000 as compensation for her services (the “**Base Salary**”). The Base Salary will be paid periodically in accordance with the Company’s normal payroll practices and be subject to the usual, required withholding. Executive’s Base Salary will be subject to review and adjustments will be made based upon the Company’s normal performance review practices.

(b) Annual Bonus. Executive will be eligible to participate in any bonus plans or programs maintained from time to time by the Company on such terms and conditions as determined by the Board or its compensation committee (the “**Committee**”), including eligibility for a bonus of up to twenty five percent (25%) of Executive’s Base Salary, upon achievement of performance objectives to be determined by the Board in its sole discretion (the “**Target Bonus**”). Any earned bonus will be paid in the next regular payroll period after the Board or the Committee determines that it has been earned, but in no event shall the bonus be paid after the later of (i) the fifteenth (15th) day of the third (3”1) month following the close of the Company’s fiscal year in which the bonus is earned, or (ii) March 15 following the calendar year in which the bonus is earned.

(c) Equity. Executive will be eligible to receive awards of stock options, restricted stock units or other equity awards pursuant to any plans or arrangements the Company may have in effect from time to time. The Board or the Committee will determine in its discretion within Executive will be granted any such equity awards and the terms of any such award in accordance with the terms of any applicable plan or arrangement that may be in effect from time to time.

5. Employee Benefits. During the Employment Term, Executive will be entitled to participate in the employee benefit plans currently and hereafter maintained by the Company of general applicability to other senior executives of the Company, including, without limitation, the Company’s group medical, dental, vision, disability, life insurance, and flexible-spending account plans. The Company reserves the right to cancel or change the benefit plans and programs it offers to its employees at any time.

6. Vacation. Executive will be entitled to receive paid annual vacation in accordance with Company policy for other senior executive officers.

7. Expenses. The Company will reimburse Executive for reasonable travel, entertainment or other expenses incurred by Executive in the furtherance of or in connection with the performance of Executive’s duties hereunder, in accordance with the Company’s expense reimbursement policy as in effect from time to time.

8. Severance. If the Company, after at least one year of service, terminates Executive's employment with the Company without Cause (excluding death or Disability) or if Executive resigns from such employment for Good Reason, and, in each case, Executive signs and does not revoke a standard release of claims with the Company in a form acceptable to the Company and subject to Section 9 below, then Executive will receive, in addition to Executive's salary payable through the date of termination of employment and any other employee benefits earned and owed through the date of termination, the following benefits from the Company:

(a) continuing payments of severance pay in accordance with the Company's normal payroll policies at a rate equal to Executive's Base Salary rate, as then in effect, for: (x) six (6) months from the date of such termination without Cause or resignation for Good Reason, if such termination or resignation occurs from today to three (3) months before a Change in Control of the Company, or (y) twelve (12) months from the date of such termination without Cause or resignation for Good Reason, if such termination or resignation occurs within three (3) months prior to, or six (6) months following, a Change in Control of the Company;

(b) if such termination or resignation occurs three (3) months prior to, or six (6) months following, a Change in Control of the Company, then one hundred percent (100%) of any Equity Awards held by Executive as of the date of such termination without Cause or resignation for Good Reason shall immediately vest and become fully exercisable (to the extent applicable);

(c) if such termination or resignation occurs within three (3) months prior to, or six (6) months following, a Change in Control of the Company, then Executive shall receive fifty percent (50%) of the Target Bonus for the year in which Executive was terminated without Cause or resigned for Good Reason; and

(d) if Executive elects continuation coverage pursuant to the Consolidated Budget Reconciliation Act of 1985 ("**COBRA**") within the time period prescribed pursuant to COBRA for Executive and Executive's eligible dependents, then the Company will reimburse Executive on the last day of each month after her employment termination date for the COBRA premiums paid during such period for such coverage (at the coverage levels in effect immediately prior to Executive's termination) for a period ending (x) three (3) months, if such termination or resignation occurs from today to three (3) months before a Change in Control of the Company, or (y) six (6) months from the date of such termination or resignation occurs within three (3) months prior to, or six (6) months following a Change of Control of the Company; provided, that such coverage shall end upon such earlier date that Executive and/or Executive's eligible dependents become covered under similar plans. Notwithstanding the foregoing, if the Company determines in its sole discretion that it cannot provide the benefit described in this Section 8(b) without potentially violating, or being subject to an excise tax under, applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company will in lieu thereof provide to Executive a taxable monthly payment, payable on the last day of a given month, in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue Executive's group health coverage in effect on the termination of employment date (which amount will be based on the premium for the first month of COBRA coverage), which payments will be made regardless of within Executive elects COBRA continuation coverage and will commence on the month following Executive's termination of employment and will end on the earlier of (A) the date upon which Executive obtains other employment or (B) the date the Company has paid an amount equal to three (3) or six (6) payments, per the terms of this agreement. For the avoidance of doubt, the taxable payments in lieu of COBRA reimbursements may be used for any purpose, including, but not limited to continuation coverage under COBRA, and will be subject to all applicable tax withholdings.

9. Conditions to Receipt of Severance; No Duty to Mitigate.

(a) Separation Agreement and Release of Claims. The payment of any severance set forth in Section 8 above is contingent upon Executive signing and not revoking the Company's standard separation and release of claims agreement upon Executive's termination of employment and such agreement becoming effective no later than sixty (60) days following Executive's employment termination date (such deadline, the "**Release Deadline**"). In no event will severance payments be paid or provided until the release actually becomes effective. Any severance payments or benefits under this Agreement will be paid on, or, in the case of installments, will not commence until, the sixtieth (60^{th}) day following Executive's separation from service, or if later, such time as required by Section 9(c). Except as required by Section 9(c), any installment payments that would have been made to Executive during the sixty (60) day period immediately following her separation from service but for the preceding sentence will be paid to Executive on the sixtieth (60^{th}) day following Executive's separation from service and the remaining payments will be made as provided in the Agreement.

(b) Confidential Information Agreement. Executive's receipt of any payments or benefits under Section 8 will be subject to Executive continuing to comply with the terms of her Confidential Information Agreement (as defined in Section 12).

(c) Section 409A.

(i) Notwithstanding anything to the contrary in this Agreement, no severance pay or benefits payable upon separation that is payable to Executive, if any, pursuant to this Agreement, when considered together with any other severance payments or separation benefits that are considered deferred compensation (together, the "**Deferred Payments**") under Section 409A of the Internal Revenue Code, as amended (the "**Code**") and the final regulations and official guidance thereunder ("**Section 409A**") will be payable until Executive has a "separation from service" within the meaning of Section 409A.

(ii) Notwithstanding anything to the contrary in this Agreement, if Executive is a "specified employee" within the meaning of Section 409A at the time of her termination (other than due to death), then the Deferred Payments, if any, that are payable within the first six (6) months following her separation from service, will become payable on the first payroll date that occurs on or after the date six (6) months and one (1) day following the date of Executive's separation from service. All subsequent Deferred Payments, if any, will be payable in accordance with the payment schedule applicable to each payment or benefit. Notwithstanding anything herein to the contrary, if Executive dies following her separation from service, but prior to the six (6) month anniversary of the separation from service, then any payments delayed in accordance with this Section 9(c) will be payable in a lump sum as soon as administratively practicable after the date of Executive's death and all other Deferred Payments will be payable in accordance with the payment schedule applicable to each payment or benefit. Each payment, installment and benefit payable under this Agreement is intended to constitute a separate payment for purposes of Section 1.409A-2(b)(2) of the Treasury Regulations.

(iii) Any severance payment that satisfies the requirements of the "short-term deferral" rule set forth in Section 1.409A-1(b)(4) of the Treasury Regulations shall not constitute Deferred Payments for purposes herein. Any amount paid under this Agreement that qualifies as a payment made as a result of an involuntary separation from service pursuant to Section 1.409A-1(b)(9)(iii) of the Treasury Regulations that does not exceed the Section 409A Limit (as defined below) will not constitute Deferred Payments for purposes herein.

(iv) For purposes of this Agreement, "**Section 409A Limit**" means the lesser of two (2) times: (x) Executive's annualized compensation based upon the annual rate of pay paid to Executive during Executive's taxable year preceding Executive's taxable year of Executive's termination of employment as determined under Treasury Regulation 1.409A-1(b)(9)(iii)(A)(1) and any Internal Revenue Service guidance issued with respect thereto, or (y) the maximum amount that may be taken into account under a qualified plan pursuant to Section 401(a)(17) of the Code for the year in which Executive's employment is terminated.

(v) The foregoing provisions are intended to comply with or be exempt from the requirements of Section 409A so that none of the severance payments and benefits to be provided hereunder will be subject to the additional tax imposed under Section 409A, and any ambiguities herein will be interpreted to so comply. Executive and the Company agree to work together in good faith to consider amendments to this Agreement and to take such reasonable actions which are necessary, appropriate or desirable to avoid imposition of any additional tax or income recognition prior to actual payment to Executive under Section 409A.

(d) No Duty to Mitigate. Executive will not be required to mitigate the amount of any payment contemplated by this Agreement, nor will any earnings that Executive may receive from any other source reduce any such payment.

10. Definitions.

(a) Cause. For purposes of this Agreement, "**Cause**" means: (i) Executive's act of personal dishonesty in connection with her responsibilities as an employee that is intended to result in Executive's substantial personal enrichment; (ii) Executive being convicted of, or pleading no contest or guilty to, (x) a misdemeanor that the Company reasonably believes has had or will have a material detrimental effect on the Company, or (y) any felony; (iii) Executive's gross misconduct; (iv) Executive's willful and continued failure to perform the duties and responsibilities of her position after there has been delivered to Executive a written demand for performance from the Company that describes the basis for the Company's belief that Executive has not substantially performed her duties and of Section 280G of the Code and (ii) but for this Section 11, would be subject to the excise tax imposed by Section 4999 of the Code, then Executive's severance benefits under Section 8 will be either:

(i) delivered in full, or

(ii) delivered as to such lesser extent which would result in no portion of such severance benefits being subject to excise tax under Section 4999 of the Code,

whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the excise tax imposed by Section 4999, results in the receipt by Executive on an after-tax basis, of the greatest amount of severance benefits, notwithstanding that all or some portion of such severance benefits may be taxable under Section 4999 of the Code. If a reduction in severance and other benefits constituting "parachute payments" is necessary so that benefits are delivered to a lesser extent, reduction will occur in the following order: (i) reduction of cash payments, which shall occur in reverse chronological order such that the cash payment owed on the latest date following the occurrence of the event triggering such excise tax will be the first cash payment to be reduced; (ii) reduction of acceleration of vesting of equity awards, which shall occur in the reverse order of the date of grant for such stock awards (i.e., the vesting of the most recently granted stock awards will be reduced first); and (iii) reduction of other benefits paid or provided to the Executive, which shall occur in reverse chronological order such that the benefit owed on the latest date following the occurrence of the event triggering such excise tax will be the first benefit to be reduced. If more than one equity award was made to the Executive on the same date of grant, all such awards shall have their acceleration of vesting reduced pro rata. In no event shall the Executive have any discretion with respect to the ordering of payment reductions.

Unless the Company and Executive otherwise agree in writing, any determination required under this Section 11 will be made in writing by a nationally recognized firm of independent public accountants selected by the Company (the "**Accountants**"), whose determination will be conclusive and binding upon Executive and the Company for all purposes. For purposes of making the calculations required by this Section 11, the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Company and Executive will furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this Section. The Company will bear all costs the Accountants may reasonably incur in connection with any calculations contemplated by this Section 11.

11. Confidential Information. Executive confirms her continuing obligations under the Company's standard At-Will Employment, Proprietary Information and Invention Assignment Agreement (the "**Confidential Information Agreement**") dated on or about the date hereof.

12. Assignment. This Agreement will be binding upon and inure to the benefit of (a) the heirs, executors and legal representatives of Executive upon Executive's death and (b) any successor of the Company. Any such successor of the Company will be deemed substituted for the Company under the terms of this Agreement for all purposes. For this purpose, "**successor**" means any person, firm, corporation or other business entity which at any time, within by purchase, merger or otherwise,

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by their duly authorized officers, as of the day and year first above written.

COMPANY:

CAPNIA, INC.

By: /s/ Anish Bhatnagar Date: December 7, 2016

Anish Bhatnagar, MD

Chief Executive Officer

EXECUTIVE:

By: /s/ Kristen Yen Date: December 7, 2016

Kristen Yen

[SIGNATURE PAGE TO KRISTEN YEN EMPLOYMENT AGREEMENT]

Exhibit 21.1

Subsidiaries of Soleno Therapeutics, Inc.

Subsidiary	Jurisdiction
Capnia, Inc.	Delaware
Essentialis, Inc.	Delaware
Soleno Therapeutics Europe Limited	Ireland
Soleno Therapeutics UK Ltd. (formerly Capnia UK Limited), a wholly owned foreign subsidiary in the United Kingdom	United Kingdom

Exhibit 23.2

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the inclusion in this Registration Statement of Soleno Therapeutics, Inc. (the "Company") on Form S-1 of our report, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, dated March 19, 2019 with respect to our audits of the consolidated financial statements of Soleno Therapeutics, Inc. as of December 31, 2018 and 2017 and for each of the two years in the period ended December 31, 2018 appearing in the annual report on Form 10-K of Soleno Therapeutics, Inc. for the year ended December 31, 2018. We also consent to the reference to our Firm under the heading "Experts" in the Prospectus, which is part of this Registration Statement.

/s/ Marcum LLP

Marcum LLP
San Francisco, CA
March 29, 2019